EXHIBIT X

SUPERIOR COURT OF THE STATE OF CALIFORNIA FOR THE COUNTY OF KERN CASE NO. S-1500-CV 279123 LHB

COLEEN M. PERRY,

PLAINTIFF

vs.

HUNG T. LUU, M.D., JOHNSON & JOHNSON, a New Jersey Corporation; ETHICON, INC., a New Jersey Corporation; and DOES 1-60, DEFENDANTS

The deposition of SCOTT A. GUELCHER, Ph.D., called by the Defendants for examination, taken before Michelle E. Kerr, RPR, a Notary Public in and for the Commonwealth of Kentucky, Daviess County, at 1719 West End Avenue, Nashville, Tennessee, on December 18, 2014, commencing at 9:40 a.m.

Golkow Technologies, Inc. - 1.877.370.DEPS

Р	age 2	Page 4
1 APPEARANCES		1 SCOTT A. GUELCHER, Ph.D.,
2 APPEARANCE FOR PLAINTIFF:		2 HAVING FIRST BEEN DULY SWORN TO TELL THE TRUTH, THE
3		3 WHOLE TRUTH, AND NOTHING BUT THE TRUTH, TESTIFIED AS
Jeffrey M. Kuntz, ESQUIRE 4 WAGSTAFF & CARTMELL		4 FOLLOWS:
4740 Grand Avenue, Suite 300		5 DIRECT EXAMINATION
5 Kansas City, MO 64112 jkuntz@wcllp.com		6 BY MR. SNELL:
6 Michael H. Bowman, ESQUIRE		7 Q State your name for the record, sir.
7 WEXLER WALLACE, LLP		8 A Scott Guelcher.
55 West Monroe Street, Suite 3300 8 Chicago, Illinois 60603		9 Q What profession are you in, Dr. Guelcher?
mhb@wexlerwallace.com		10 A I'm an Associate Professor of Chemical
10 APPEARANCE FOR DEFENDANT: Hung T. Luu, M.D.		11 Engineering at Vanderbilt University.
(Via Telephone)		12 Q You understand we're here today to take your
Zachary S. Rosen, ESQUIRE		deposition in the Coleen Perry case, which is
12 BOYCE SCHAEFFER MAINIERI, LLP 500 Esplanade Drive, Suite 950		14 currently pending in California?
13 Oxnard, California 93036		15 A I do.
zrosen@boyceschaefferlaw.com 14		16 Q And you're here today to give your opinions
15 APPEARANCE FOR DEFENDANTS: Johnson & Johnson and Ethicon, Inc.		and the bases for those opinions, correct?
16		18 A Yes.
Nils B. (Burt) Snell, ESQUIRE 17 BUTLER SNOW, LLP		19 Q When were you first contacted to serve as an
500 Office Center Drive, Suite 400 18 Fort Washington, Pennsylvania 19034		20 expert in the Perry case?
burt.snell@butlersnow.com		21 A I believe it was September, September '14.
19 20		22 Q So in September of 2014, you were contacted
21		to be an expert in the Perry case?
22 23		24 A That's what I remember.
24 25		25 Q Who were you contacted by?
	age 3	Page 5
1 INDEX		1 A By plaintiff's counsel, Jeff Kuntz and Tom
PAGE		2 Cartmell.
2 Direct Examination by Mr. Snell 4		3 Q And what did you understand your assignment
3		to be in relation to the Coleen Perry case?
Cross-Examination by Mr. Rosen 265		5 A Assignment, I'm not sure what you mean by
Cross-Examination by Mr. Kuntz 265		6 that.
5 Redirect Examination by Mr. Snell 267		7 Q What did you understand your purpose was to
6		be as an expert involved in the Perry case?
7 8		9 A Well, I was testifying about defects in the
9 10 EVHIDITS		10 Abbrevo mesh.
10 EXHIBITS PAGE		11 Q Did you say effects?
11		12 A Defects in the Abbrevo mesh product.
1 - Article by Clave 49		13 Q You have given other deposition and trial
2 - Pathology Slides - Coleen Perry 90		testimony in mesh litigation, correct?
13 (Three Sets) 14 3 - Thumb Drive Containing Reliance 150		15 A Yes, I have.
Documents		16 Q You testified in the Huskey case that
15 4 - Summary of Opinions by Dr. Guelcher 192		involved Ethicon's TVT-O product, correct?
16		18 A I did.
5 - Document Containing Listing of 241 17 Cases		19 Q You were deposed and gave trial in West
18 6 - Curriculum Vitae 242		20 Virginia, correct?
19 7 - Printout from Vanderbilt University 257 Medical Center Website		21 A That's correct.
20		22 Q And at the time that you gave that testimony,
21 22		23 it was under oath as well, correct?
23		24 A That's correct.
24 25		25 Q And did you tell the truth in that testimony?

2 (Pages 2 to 5)

	Page 6		Page 8
1	A Yes.	1	Huskey case. Do you recall giving that
2	Q How many hours have you spent on the Perry	2	testimony?
3	case?	3	MR. KUNTZ: Objection.
4	A I'm not sure. I haven't billed any invoices	4	A I'm not sure what you mean by a cut.
5	for time yet, so I don't know the total	5	BY MR. SNELL:
6	number of hours.	6	Q In the Huskey case, as I recall it, you
7	Q Can you give me your best estimate?	7	received \$200 per hour for review and work,
8	A I don't know. Maybe 20. But when I submit	8	correct?
9	my invoices, that will be the more reliable	9	A I don't believe that's well, it was 200 or
10	number. I haven't added it up yet.	10	210. He raised the rates. Okay. It was 200
11	Q Well, do you have the invoices on your	11	or 210. The rates have been changed, and I
12	calendar?	12	don't remember if it was before or after
13	A No.	13	Huskey. It may have been 200. It may have
14	Q In the Huskey case, you testified that you	14	been 210. I can't remember.
15	submitted your invoices to Dr. Dunn in	15	Q And Dr. Dunn billed \$275 an hour for your
16	connection with that matter. Do you recall	16	review time, correct?
17	giving that testimony?	17	A If I bill 200, then Dr. Dunn would have
18 19	A That's correct.	18 19	billed 275.
20	Q Are you submitting your invoices to Dr. Dunn in the Perry case?	20	Q And is it your testimony that that
21	A I'm not sure yet how that will be. I'll be	21	arrangement has changed within the last one to two months?
22	billing my plan is it's not resolved	22	A Yes. I have not submitted any invoices for
23	yet, whether I will independently or through	23	this case, but the plan for moving forward is
24	Dr. Dunn's company.	24	for me to submit invoices independent of
25	Q How do you track your time that you spend in	25	Dr. Dunn's company.
	Page 7		Page 9
1	the Perry case?	1	Q Do you have your own company that you will be
2	A I have some paper records, but it's not	2	submitting invoices under?
3	nothing is official. I've not been	3	A I do.
4	releasing in the past, all the invoices	4	Q What's the name of that company?
5	have been submitted through Dr. Dunn's	5	A Guelcher Consulting, LLC.
6	company. Nothing is official until I submit	6	Q In the Huskey matter, you testified that you
7	the invoices. I don't have the invoices	7	kept a calendar and a recording of your time
8	right now.	8	spent and the days that you worked as an
9	Q Well, in the Huskey case, you testified under	9	expert. Do you recall giving that testimony?
10	oath that you submitted monthly invoices to	10	A I do.
11	Dr. Dunn, which included the time spent, the	11	Q Have you done the same thing here?
12	time of day spent and a brief description of	12	A I have not. Not in the same way.
13	your activities. Do you recall giving that	13	Q Why not?
14	testimony?	14	A I just changed it. I have a right to change
15	A I do.	15	the way I keep the time.
16 17	Q And at what point in time has that changed?A Very recently. In the past maybe month or	16 17	Q So what materials or documents do you have that would reflect the time you've spent up
18	two.	18	until the time of this deposition for the
19	Q When was the last time you sent an invoice to	19	Perry case?
20	Dr. Dunn with regard to your work as an	20	A I don't have them yet because I haven't
21	expert in mesh litigation?	21	submitted the invoices. That's what I said.
22	A I don't remember. Maybe a month or two ago.	22	Q I'm not asking about invoices.
23	I don't remember the date.	23	I'm asking what other materials or
24	Q As I understand it, Dr. Dunn received a cut	24	documents what would you look to to draft
25	from the amount billed for your work in the	25	an invoice so that you would know the

3 (Pages 6 to 9)

	Page 10		Page 12
1	accurate amount of hours for your billing	1	Q For over a year, you submitted invoices
2	that you would submit?	2	through Dr. Dunn and his company, correct?
3	A I have some paper at home.	3	A That's correct.
4	Q What paper at home?	4	Q Is it your testimony that there was nothing
5	A Well, I have a piece of paper that has hours	5	that made you decide to go out and become
6	written on it, but I haven't added everything	6	independent of Dr. Dunn?
7	up yet because I haven't submitted the	7	A Well, that's not what you asked me the first
8	invoice.	8	time. You ask me what happened, implying
9	Q Is this a piece of paper in a notebook or	9	that something disruptive happened in our
10	A No, it's just a note.	10	working relationship, which nothing happened.
11	Q Do you have a copy of that that you can give	11	It's just a decision to do this
12	to counsel?	12	independently.
13	A No, I don't, because we haven't been doing	13	Q How much are you billing now for your work
14	that. We've been providing invoices, and	14	A The same rate.
15	Dr. Dunn was providing invoices, and I just	15	Q Let me finish my question.
16 17	don't have an invoice yet that I've sent in.	16 17	A Sure.
18	Until it's finalized, I don't I've not been submitting records of time until there	18	Q How much are you billing for your time as an expert in the Perry case for review of
19	is a final invoice.	19	materials?
20	MR. SNELL: Well, I'm going to	20	A The same rates as Dr. Dunn.
21	make a request that you get a copy of that to	21	Q Can you tell me how much per hour?
22	counsel, and we'll attach it to the	22	A Dr. Dunn raised his rates from 275 to 285 for
23	deposition.	23	report writing, reviewing of documents, etc.
24	MR. KUNTZ: We'll get you a	24	I will be charging that rate. For testimony,
25	copy.	25	I just can't remember the number right now.
	Page 11		Page 13
1	A I can send an invoice after today and that	1	I think it's maybe 385 is a number for
2	will make it official. Is that okay?	2	testimony, but that would be on the invoice.
3	BY MR. SNELL:	3	I can't remember the number right now.
4	Q Well, that's fine. But I'd like to know what	4	Q So it's your intention to bill \$285 per hour
5	it is because I will have questions about	5	for reviewing materials and report writing
6	that potentially.	6	and things like that?
7	A What is? I don't understand. You said you'd	7	A That's what Dr. Dunn was billing. And since
8	like to know what it is if I send you an	8	I'm doing the same activities, I thought it
9	invoice. You know what it is. It's an	9	reasonable to bill the same rate.
10	invoice that says my hours and what I did, so	10	Q Dr. Dunn is not an expert in this case.
11	I'm not sure what you're looking for.	11	You're aware of that, correct?
12	Q Well, right now you currently have you	12	A My understanding is that Dr. Dunn has not
13 14	testified you have a document that has your	13 14	been produced as an expert witness for Plaintiffs.
15	hours and the time you spent. That's the document I would like. If you draft an	15	Q All right. So for you I just want to get
16	invoice, I would like that as well.	16	a clean answer without injecting Dr. Dunn
17	A Okay.	17	into this Q and A. The rates that you,
18	Q When did you form Guelcher Consulting, LLC?	18	Dr. Guelcher, are charging for report writing
19	A It's been very recent. In the past few weeks	19	and review of documents for this matter in
20	maybe.	20	the Perry case will be \$285 per hour; is that
21	Q What happened between you and Dr. Dunn that	21	correct?
22	led you to believe that you should go out	22	A That's correct.
23	independent of Dr. Dunn?	23	Q The rate that you will charge for testimony,
24	A Nothing happened with Dr. Dunn. I'm not sure	24	as best as you can figure at this point in
25	what you're asking me.	25	time, is \$385 per hour?

4 (Pages 10 to 13)

	Page 14		Page 16
1	A That's correct.	1	have you ever spoken to him?
2	Q Will you have a different rate for trial	2	A No.
3	testimony if you are called to testify at	3	Q Okay. Dr. Donald Marks, he is another
4	trial?	4	expert
5	A I don't believe so. I intend to use the same	5	A I have not.
6	rates that were being billed in the past, and	6	Q You have not spoken with him?
7	there was no difference between trial and	7	A No.
8	deposition testimony. Those numbers were the	8	Q Have you reviewed any expert reports or
9	same. So whatever those numbers are, it will	9	expert declarations in the Perry case?
10	be the same. There won't be a difference.	10	A Yes.
11	Q You understand that this trial will be in	11	MR. KUNTZ: Aside from this own?
12	California?	12	MR. SNELL: Yes, of course.
13	A Yes.	13	BY MR. SNELL:
14	Q And you're agreeable to traveling to	14	Q Let me just take that off the table and
15	California for trial?	15	reformulate.
16	A Yes.	16	Setting aside your expert declaration
17	Q Your expenses of traveling to California,	17	listed opinions, have you reviewed any other
18	would you bill for those?	18	experts' declarations or listed opinions?
19	A That's what Dr. Dunn has done in the past,	19	A Declarations, no, I don't believe so.
20	and I would continue that practice.	20	Q Okay. For your opinions in this case, you're
21	Q So if you come to trial in California, you	21	not relying on the declarations or reports of
22	will bill for your expenses, such as air	22	any other experts, correct?
23	fare, and hotel room, and meals, correct?	23	A No, I'm not relying on any other
24	A Yes, that's correct.	24	declarations.
25	Q Have you ever met Mrs. Perry?	25	Q You're not relying on any other experts'
	Page 15		Page 17
1	A I have not.	1	opinions, correct?
2	Q Have you spoken to Mrs. Perry?	2	A Yes.
3	A I have not.	3	Q Do you know if any independent medical
4	Q Have you ever spoken to any of Mrs. Perry's	4	examinations have been done on Mrs. Perry?
5	family or friends?	5	A I'm not aware of any of those outcomes of
6	A No.	6	those medical examinations. I've not
7	Q Have you ever spoken with any of Mrs. Perry's	7	reviewed that.
8	doctors?	8	Q So you haven't reviewed any of the IME
9	A No.	9	outcomes or reports in this Perry case,
10	Q Okay. Have you spoken with any other experts	10	correct?
11	about the Perry case?	11	A No.
12	A Any other experts defined as	12	Q I'm not correct?
13	Q Defined as let me ask you this. Besides	13	A I have not reviewed, yeah. I'm sorry.
14	yourself, who do you understand to be the	14	Q Okay. And you're not relying on the outcomes
15	other experts besides yourself in the Perry	15	of any IME reports; is that correct?
16	case?	16	A Yes, that's correct.
17	A I don't know who the other experts are that	17	Q When you do issue your invoices or invoice
18	they are calling. I haven't spoken with	18	for the Perry case, will the check be made
19	them.	19	payable to Guelcher Consulting, LLC, or to
20	Q So you have not spoken with a Dr. Rosenzweig	20	you personally?
21	about the Perry case?	21	A It will be made to the LLC. I'm the sole
22	A I have not.	22	owner of the LLC, so it will be made to the
23	Q Have you ever spoken with Dr. Rosenzweig?	23	LLC.
24	A I have not.	24	Q Is Guelcher Consulting, LLC, a Tennessee
25	Q Dr. Michael Thomas Margolis from California,	25	corporation?

5 (Pages 14 to 17)

	Page 18		Page 20
1	A Yes. It's been registered with the secretary	1	course on polymer science and engineering at
2	of state.	2	Vanderbilt.
3	Q As I understand it from your testimony at	3	Q In prior cases, as I understand it, and have
4	Huskey and other matters, you believe your	4	read your testimony, Dr. Dunn, if testing was
5	expertise is in the field of biomaterials	5	done, he would have been the one to perform
6	design?	6	the testing on meshes?
7	A That's one way of saying it. I have	7	A That's correct, Dr. Dunn did the testing.
8	expertise in biomaterials science and	8	Q Is there a certain reason for that?
9	engineering. Another way you could say it is	9	A The reason relates to the nature of our
10	that my work involves design of materials for	10	employments at Vanderbilt. Dr. Dunn is a
11	use as bone grafts or skin grafts, design of	11	professor of the practice. I'm a tenured
12	biomaterials as diagnostics for studying	12	associate professor with a federally-funded
13	cancer metastasis.	13	research program. And so we have different
14	Q You have a Ph.D., correct?	14	appointments, that's the reason.
15	A Yes.	15	Q I don't understand that.
16	Q Any higher education than that?	16	Can only professors do the type of
17	A I did a postdoctoral research training at	17	testing that he performed in the prior cases?
18	Carnegie Mellon in biomedical engineering.	18	A I'm qualified to do the testing. It's that I
19	Q But that was not something for which a degree	19	have graduate students working in my
20	was earned; is that correct?	20	laboratory on federal research grants.
21	A It's not a degree, but it's postdoctoral	21	Dr. Dunn has a company with employees. It's
22	training. It counts as training.	22	simpler for him to do the testing than for me
23	Q You're not a medical doctor, correct?	23	from an administrative perspective. So that
24	A No, I'm not a medical doctor.	24	doesn't have anything to do with
25	Q You're not a pathologist?	25	qualifications or ability. It's more because
	Page 19		Page 21
1	A I'm not a pathologist.	1	of these practical reasons.
2	Q You don't treat any patients, correct?	2	Q So you have graduate students working under
3	A I don't treat patients.	3	you who are being subsidized, whose work is
4	Q You're not a toxicologist, correct?	4	being subsidized by federal funding; is that
5	A I'm not a toxicologist.	5	correct?
6	Q What is the difference between your expertise	6	A I wouldn't say it's being subsidized. The
7	and Dr. Dunn's expertise?	7	work is being funded by federal funding, and
8	A So Dr. Dunn and I have overlapping expertise	8	in some cases, by corporate funding. Their
9	in polymer science and engineering. My	9	stipends are paid either from fellowships or
10	expertise is differentiated from Dr. Dunn's	10	from the grants, not from the consulting.
11	in biomaterials, preclinical testing of	11	Q Okay. Well, what about the fact of graduate
12	biomaterials, evaluation of biomaterials	12	students working under you who are supported
13	using in vitro and in vivo models. Those	13	by federal funding, what affect does that
14 15	would be some examples of how my expertise is differentiated from Dr. Dunn's.	14 15	have on why Dr. Dunn did the testing and you didn't?
16	Q Is Dr. Dunn more of a polymer chemist than	16	A Well, to have graduate students working on
17	you are?	17	that sort of testing would require a
18	A I would not state it this way. I've had	18	disclosure to the university, so I haven't
19	extensive experience in polymer chemistry,	19	had them involved. I've disclosed the
20	science and engineering. I've worked for	20	consulting activity to the university
21	several companies in the area of polymers.	21	required by the policy, but to have graduate
22	My postdoctoral training was in polymers for	22	students involved would require more, and I
23	bone scaffolds. And for the past ten years	23	just haven't done that at this time.
24	at Vanderbilt, I've been working on polymers	24	Q What type of disclosure did you make to the
25	and I taught and I developed and taught a	25	university with regard to your goal as an

6 (Pages 18 to 21)

	Page 22		Page 24
1	expert witness?	1	A That's a complex question. It depends on
2	A Every year we are required to file a	2	what's being used and the specific faculty
3	disclosure report that would include	3	member. It would have to be discussed with
4	because I have NIH grants, the NIH requires	4	the university. I don't know the answer to
5	us to disclose travel funded by third	5	that. There is not a fixed answer to that
6	parties. I'm required to disclose	6	question.
7	relationships with companies that I have had	7	Q If you have one of your graduate students who
8	grants from companies in the past, consulting	8	is supported by federal funding analyze
9	relationships with companies. These	9	meshes from the mesh litigation, would you
10	activities are disclosed.	10	have to disclose that to anyone?
11	In the past what I've disclosed is that I	11	A I would discuss that with the dean's office.
12	was a consultant working for Polymer and	12	But Dr. Dunn's company did the testing, so
13	Chemical Technologies.	13	Q Where is Dr. Dunn's company located at?
14	Q So your disclosure stated that you worked as	14	A At his residence in Nashville.
15	a consultant in polymer and	15	Q He has employees working out of his home in
16	A For Polymer and Chemical Technologies.	16	Nashville?
17	That's Dr. Dunn's company. So last year's	17	A I can't speak to those details about
18	disclosure, that's what I have filed. I have	18	Dr. Dunn's company. I don't know how he
19	to update it this year again.	19	operates his company other than his business
20	Q Did you identify in your disclosure that you	20	relationship with me.
21	were serving as an expert on behalf of	21	Q Do you know if Dr. Dunn utilized any of the
22	plaintiffs in the transvaginal mesh	22	graduate students at Vanderbilt in any
23	litigation?	23	analyses pertaining to transvaginal mesh?
24	A We're not required to disclose the activity,	24	A Not to my knowledge.
25	only the fact that we're consulting.	25	Q Do you know if Dr. Dunn utilized any
23	Page 23	23	Page 25
1			
1	Q So you did not disclose that you were	1	Vanderbilt personnel besides yourself in any
2	consulting with plaintiffs' attorneys in	2	analyses or investigation pertaining to
3	transvaginal mesh litigation?	3	transvaginal mesh?
4	A I don't remember what I disclosed right now,	4	A Again, Dr. Dunn would have to speak to that.
5	the exact details. I disclosed that I had a	5	I don't know.
6	consulting relationship. I don't remember	6	Q Who is your immediate supervisor currently?
7	the detail of what I exactly disclosed. I	7	A My department chair, Kane Jennings.
8	would have to look at it again.	8	Q Could you spell that?
9	Q Now, that you're billing your services	9	A K-A-N-E Jennings.
10	directly through your own corporation, are	10	Q And that's within the department of what?
11	you going to disclose that you are consulting	11	A Chemical and biomolecular engineering.
12	and serving as an expert to plaintiffs in	12	Q So you work within the Department of Chemical
13	transvaginal mesh litigation?	13	and Biomolecular Engineering at Vanderbilt?
14	A When I submit the invoices, I will update the	14	A That is correct.
15	disclosure, but that hasn't been finalized	15	Q Is that a particular school at Vanderbilt?
16	yet. When I submit the invoices, I will	16	A That department is within the school of
17 18	update the disclosure.	17	engineering. Q Besides Dr. Dunn, who, if anyone else at
ı ı X	•		LL Recided Dr. Llunn, who it anyone else at
	Q Where does this disclosure get submitted to	18	
19	Q Where does this disclosure get submitted to within Vanderbilt?	19	Vanderbilt is aware that you are serving as
19 20	Q Where does this disclosure get submitted to within Vanderbilt?A At the dean's office, dean of engineering.	19 20	Vanderbilt is aware that you are serving as an expert for plaintiffs in the transvaginal
19 20 21	Q Where does this disclosure get submitted to within Vanderbilt?A At the dean's office, dean of engineering.Q If you do any testing of meshes in your role	19 20 21	Vanderbilt is aware that you are serving as an expert for plaintiffs in the transvaginal mesh litigation?
19 20 21 22	 Q Where does this disclosure get submitted to within Vanderbilt? A At the dean's office, dean of engineering. Q If you do any testing of meshes in your role as a plaintiff's expert, and you utilize any 	19 20 21 22	Vanderbilt is aware that you are serving as an expert for plaintiffs in the transvaginal mesh litigation? A Professor Ken Debelak, D-E-B-E-L-A-K. He's
19 20 21 22 23	 Q Where does this disclosure get submitted to within Vanderbilt? A At the dean's office, dean of engineering. Q If you do any testing of meshes in your role as a plaintiff's expert, and you utilize any of Vanderbilt's equipment, personnel, or any 	19 20 21 22 23	Vanderbilt is aware that you are serving as an expert for plaintiffs in the transvaginal mesh litigation? A Professor Ken Debelak, D-E-B-E-L-A-K. He's an Associate Professor of Chemical and
19 20 21 22	 Q Where does this disclosure get submitted to within Vanderbilt? A At the dean's office, dean of engineering. Q If you do any testing of meshes in your role as a plaintiff's expert, and you utilize any 	19 20 21 22	Vanderbilt is aware that you are serving as an expert for plaintiffs in the transvaginal mesh litigation? A Professor Ken Debelak, D-E-B-E-L-A-K. He's

7 (Pages 22 to 25)

	Page 26		Page 28
1	an expert in prior litigation over a year	1	solution of 20 percent hydrogen peroxide with
2	ago. I believe Dr. Debelak was deposed in	2	cobalt chloride, and I don't remember the
3	this first case, but not since.	3	exact amount. That's the solution.
4	Q Have you had anyone at Vanderbilt perform any	4	Q And this solution is used for the in vitro
5	activity on your behalf with regard to	5	testing of mesh?
6	anything you've done in the transvaginal mesh	6	A This solution was first developed by Dr. Jim
7	litigation as an expert?	7	Anderson in 1993. It was first published
8	A So I have a graduate student who was doing	8	his group published a number of papers on it.
9	oxidative degradation testing through her	9	I published two papers with it. It's used to
10	dissertation project, and she provided	10	assess the degradation of biomaterials under
11	well, I asked my graduate students to write	11	oxidative conditions that are similar to
12	standard operating procedures for everything	12	those in the human body, more specifically,
13	we do. I review and discuss those procedures	13	that are similar to those under conditions
14	with them and approve them, and she gave that	14	where there are adherent inflammatory cells
15	protocol to Professor Dunn.	15	in the biomaterial, the foreign body
16	Q What's the name of this graduate student?	16	reaction, I should say, the effects of the
17	A Anne Talley, T-A-L-L-E-Y.	17	foreign body reaction on the stability of the
18	Q Let me see if I understand this. So you	18	biomaterial.
19	asked all of your graduate students to write	19	It's a very general well-known
20	SOP's?	20	established test that's been cited dozens of
21	A So for anything that we do in the laboratory,	21	times.
22	for any polymer that we make, for any	22	Q So did Ms. Talley or any of your other
23	analysis that we run, such as oxidative	23	graduate students do any in vitro testing on
24	degradation testing, we review the literature	24	the mesh?
25	and prepare a standard operating procedure or	25	A No. As I said before, that testing was done
	Page 27		Page 29
1	an SOP for the procedure, and I believe	1	by Dr. Dunn's company.
2	that's part of student training. These are	2	Q Was the testing done by Dr. Dunn's company
3	the types of activities they will do in the	3	before or after Ms. Talley's SOP was given to
4	industry, so I ask my students to write these	4	Dr. Dunn?
5	types of documents.	5	A I believe it was after, because they used
6	Q What did you ask Anne Talley to do	6	that SOP to prepare the solution. These
7	specifically that pertained to your work as	7	activities were done by Dr. Dunn, but I don't
8	an expert in the transvaginal mesh	8	know who in his company did what. I just
9	litigation?	9	know that my lab through Anne provided them
10	A I didn't ask her I asked her to write the	10	with a solution with a strike that with
11	SOP for the medium, preparing the medium.	11	an SOP for preparing the solution, and then
12	And then Dr. Dunn asked her for that SOP is	12	they did the testing.
13	my understanding.	13 14	Q Did Ms. Talley know that she was writing an SOP that would be given to plaintiffs'
14 15	Q Why did you ask Ms. Talley to write the SOP	15	<u> </u>
16	for the preparation of the medium? A Well, she was the one that was working in	16	experts in the transvaginal mesh litigation for utilization in certain testing?
17	this area on her research project, so she had	17	A She did not prepare the SOP for plaintiffs.
18	the most knowledge about it.	18	She prepared the SOP for use in my
19	Q When you say medium, what medium are you	19	laboratory. She was aware of the mesh
20	referencing?	20	litigation, but she was not she did not
21	A The medium that was used in the in vitro	21	write it for this. It's an SOP for my
22	testing with the mesh.	22	laboratory. It falls within the scope of her
23	Q What was that medium?	23	activities on her funded research project.
24	A It's a solution of 20 percent cobalt chloride	24	MR. SNELL: Move to strike.
25	I'm sorry. Strike that. It was a	25	BY MR. SNELL:

8 (Pages 26 to 29)

	Page 30		Page 32
1	Q Did Ms. Talley know that she was preparing an	1	this SOP?
2	SOP that would be given to a plaintiff's	2	A I don't remember. I don't know when exactly
3	expert for use in transvaginal mesh	3	she wrote it or when it was revised or
4	litigation?	4	finalized. I don't remember.
5	A The way you asked that question, no, I don't	5	Q Well, was it this year or last year?
6	believe so. It was written for my	6	A I don't know.
7	laboratory. She did not write it for the	7	Q When did Dr. Dunn do this testing that he
8	testing. It's an SOP that was in my	8	utilized Ms. Talley's SOP that she wrote
9	laboratory.	9	while as a graduate student for you?
10	Q How long did it take Ms. Talley to write this	10	A It was done in September.
11	SOP?	11	Q Of 2014?
12	A I don't know.	12	A Yeah.
13	Q Did you assign Ms. Talley to write this	13	Q So, certainly, Ms. Talley would have been
14	particular SOP regarding this testing?	14	working on this SOP during the calendar year
15	A I believe so. I asked her to write the SOP	15	of 2014, correct?
16	for the procedure in general to use in our	16	A She would have been working on it.
17	lab. We use it for other projects as well.	17	Typically, these are documents that we write
18	Q You were aware when you asked Ms. Talley to	18	and we revise, so I have had students write
19	write the SOP regarding the testing, that it	19	SOP's, and then other students come back and
20	would be used by Dr. Dunn in his role as an	20	revise them. That's how we do it. We revise
21	expert for plaintiffs in the mesh litigation?	21	them based on new papers that have been
22	A I was aware of that.	22	published, new information, so I don't know
23	Q Did Dr. Dunn give Ms. Talley any money or	23	the history of the document. I can't
24	renumeration for writing this SOP that he	24	remember that.
25	used in his role as an expert in the mesh	25	Q Is Ms. Talley currently a graduate student at
	Page 31		Page 33
1	litigation?	1	Vanderbilt?
2	A He wouldn't give her renumeration because it	2	A Yes.
3	was written within the course of her work at	3	Q If you had done any of the types of testing
4	Vanderbilt and her project.	4	that Dr. Dunn has performed in his role as an
5	Q So the answer is, no, he didn't give her any	5	expert in the transvaginal mesh litigation on
6	money?	6	the mesh, what type of paperwork or
7	A No.	7	disclosures would you have had to give to
8	Q And did you give Ms. Talley any money or	8	Vanderbilt?
9	renumeration for writing the SOP that you	9	A I don't know. It's difficult to answer these
10	were aware of that would be used in testing	10	questions. We tend to address them when
11	meshes in transvaginal litigation?	11	I just as I said earlier, I have not been
12	A I didn't give her money because it was	12	doing testing of materials for litigation at
13	written for her research project for her work	13	Vanderbilt, so I don't know what I would have
14	at Vanderbilt.	14	to do. So far I've disclosed the consulting
15	Q So the answer is no, you didn't give her any	15	activity. I may very will make additional
16	money, correct?	16	disclosures as we move along and the
17	A No, but for that reason. It wasn't written	17	situation changes, but it's a very fluid
18	for the mesh litigation.	18	situation.
19	Q Other than Ms. Anne Talley, have you involved	19	We disclose these types of things as they
20	any of your other graduate students in any	20	arise. So it's difficult to say without
21	testing or analyses pertaining to your work	21	actually seeing the situation.
22	as an expert in the transvaginal mesh	22	Q Does Vanderbilt require you to disclose any
23	litigation?	23	relationships upon which you receive outside
24	A No.	24	monies?
25	Q How long ago was it that Ms. Talley wrote	25	A I already answered this. We're required to

9 (Pages 30 to 33)

	Page 34		Page 36
1	disclose consulting relationships. When I	1	independent role now as an expert and
2	submit a grant application, I'm required to	2	billing as an expert will have on your
3	disclose whether I have a significant	3	ability to work or run a lab that has
4	financial interest. The NIH changed the	4	federally-funded research?
5	rules in 2012. I disclose whether there is a	5	A Yes, I have.
6		6	
7	significant financial interest, and then the	7	Q And what affect, if any, have you learned about that?
8	dean's office works with me to figure out if	8	
9	there is a conflict, and if there is, how do		A I'm contemplating updating my disclosure.
10	we manage it.	9	And well, I will leave it at that.
11	So there is no fixed set procedure. It's		Q Have you had any discussions with anyone at
	very much handled on a case-by-case basis.	11	Vanderbilt about ways you could work around
12	And disclosures are continuously updated as	12	the ramifications that the receipt of federal
13	new information becomes available.	13	funding has on your role as an expert?
14	Q How is significant financial interest	14	MR. KUNTZ: Objection.
15	defined?	15	A I don't like this word work around. That's
16	A The NIH defines a significant financial	16	not what we do. We identify conflicts. We
17	interest as \$5,000 a year. That's one way to	17	disclose information to the dean's office.
18	define it. Another is equity. Strike that.	18	We work with the dean's office to identify
19	The NIH defines it as \$5,000 or greater.	19	conflicts. If conflicts are identified, we
20	Financial interest, that could be cash. That	20	work with the dean's office and the general
21	could be equity. That could be any form of	21	counsel's office to identify and manage a
22	compensation, but the threshold is \$5,000.	22	plan, which is then approved approved by
23	Q Have all monies you receive in your role as	23	the conflict of interest committee.
24	an expert in the transvaginal mesh litigation	24	I've been through this process multiple
25	for the calendar year 2014 been paid to you	25	times. I've had management plans. I've been
	Page 35		Page 37
1	through Dr. Dunn's company?	1	disclosing conflicts to Vanderbilt since I
2	A The money I have received has all been	2	started there. There is a very standard and
3	received through Dr. Dunn's company, that's	3	routine process. Faculty are allowed and
4	right, yes. The money I received, yes.	4	encouraged to participate in activities
5	Q Does anyone at Vanderbilt know the scope of	5	outside of Vanderbilt. I do this in the
6	Dr. Dunn's company?	6	course of my research with licensing,
7	A I can't speak to Dr. Dunn's company. I don't	7	start-up companies. This is routine.
8	know the details of his arrangement with the	8	There is a process and a procedure. And
9	university. I just don't. He has a	9	we're not working around anything. We're
10	different type of appointment than I have.	10	trying to find a way to work within the
11	He doesn't do federally-funded research.	11	framework of the federal regulations and
12	That's what I know. I don't know the details	12	university policy. It's very standard for
13	of his arrangement with Vanderbilt.	13	universities.
14	Q Is Dr. Dunn in a position of authority over	14	BY MR. SNELL:
15	you at Vanderbilt?	15	Q Have you told Vanderbilt how much money you
16	A No.	16	have earned as an expert in the transvaginal
17	Q If Dr. Dunn wanted to do federally-funded	17	mesh litigation?
18	research, would he be able to in light of his	18	A You have asked me this before. And I said we
19	activities and the amount of money his	19	are not required in the course of our work to
20	company bills for expert work in the	20	disclose that. If I believe that I see a
21	transvaginal mesh litigation?	21	conflict between my research and the
22	A I can't speak to that. I don't know how much	22	consulting, then I will disclose that and the
23	his company bills or makes. I don't know	23	university will we will have those
24	that information.	24	discussions, but we are not required to
25	Q Have you investigated what affect your	25	disclose this information for consulting

10 (Pages 34 to 37)

	Page 38		Page 40
1	work.	1	if and when I submit a grant application,
2	Q So the answer to my question is, no, you have	2	that would create the conflict, but that's
3	not disclosed that to Vanderbilt, correct?	3	tied to INH funding. That's not why I'm
4	A I'm not required strike that.	4	not required to disclose it unless there is a
5	Q My question is simple. Have you disclosed to	5	conflict of the federally-funded research
6	Vanderbilt	6	project.
7	A And I believe I have answered your question.	7	Q Have you performed any testing on Ms. Perry's
8	Q I think you are telling me about what you're	8	mesh?
9	required to do.	9	A I have not.
10	I'm asking you, have you, Dr. Guelcher,	10	Q Have you looked at Ms. Perry's mesh under a
11	disclosed to Vanderbilt the monies, the	11	scanning electron microscope?
12	amount of monies you have earned as a	12	A I have not.
13		13	Q What are all of the different tests, methods
14	plaintiff's expert in transvaginal mesh	14	
15	litigation?	15	that one can do to try to determine whether
16	MR. KUNTZ: Object. Answer it. BY MR. SNELL:	16	there is degradation of polypropylene?
17		17	A So degradation of polypropylene could be
18	Q It's a yes or no answer.	18	assessed by SEM imaging. That's typically
	A No, I've not disclosed, but I'm not		how we assess it.
19 20	Q Have you informed your dean of your current	19	Q FTIR
	intention to bill as an independent	20	A FTIR I'm sorry.
21	consultant to attorneys in the transvaginal	21	Q FTIR is a way that one can go about trying to
22	mesh litigation?	22	assess whether there is degradation of
23	A Why would I inform the dean of this? I've	23	polypropylene, correct?
24	not informed the dean. I have to inform the	24	A No, that's not why we use FTIR. We use FTIR
25	dean when I believe there is a conflict. And	25	to assess for oxidation, chemical changes in
	Page 39		Page 41
1	if and when I make that assessment, I will	1	Page 41 the polypropylene. That can be assessed by
1 2	-	1 2	
	if and when I make that assessment, I will		the polypropylene. That can be assessed by
2	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things.	2	the polypropylene. That can be assessed by the FTIR.
2 3	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do	2 3	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR,
2 3 4	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things.	2 3 4	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there
2 3 4 5	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at	2 3 4 5	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to
2 3 4 5 6	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000.	2 3 4 5 6	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct?
2 3 4 5 6 7 8	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater	2 3 4 5 6 7	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer
2 3 4 5 6 7	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an	2 3 4 5 6 7 8	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface
2 3 4 5 6 7 8 9	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to	2 3 4 5 6 7 8 9	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we
2 3 4 5 6 7 8 9	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need	2 3 4 5 6 7 8 9	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra
2 3 4 5 6 7 8 9 10	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection.	2 3 4 5 6 7 8 9 10	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal
2 3 4 5 6 7 8 9 10 11 12	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean?	2 3 4 5 6 7 8 9 10 11	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene.
2 3 4 5 6 7 8 9 10 11 12 13	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The	2 3 4 5 6 7 8 9 10 11 12	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized
2 3 4 5 6 7 8 9 10 11 12 13 14	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research,	2 3 4 5 6 7 8 9 10 11 12 13	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing
2 3 4 5 6 7 8 9 10 11 12 13 14 15	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit	2 3 4 5 6 7 8 9 10 11 12 13 14 15	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal funding. I have to answer the question, do	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene? A And why is that I don't know what you're
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal funding. I have to answer the question, do you have a significant financial interest in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene? A And why is that I don't know what you're referring to.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal funding. I have to answer the question, do you have a significant financial interest in the outcome of this federally-funded project.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene? A And why is that I don't know what you're referring to. Q I recall in your Huskey testimony, in your
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things. Q Well, if you spent approximately 20 hours at \$285 an hour thus far, that is over \$5,000. Are you telling me that if you have a greater than \$5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean? MR. KUNTZ: Objection. A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal funding. I have to answer the question, do you have a significant financial interest in the outcome of this federally-funded project. Significant financial interest is defined	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	the polypropylene. That can be assessed by the FTIR. Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct? A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene. Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene? A And why is that I don't know what you're referring to. Q I recall in your Huskey testimony, in your deposition, you testified that all of the
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11 (Pages 38 to 41)

	Page 42		Page 44
1	did for the Huskey trial. I do believe we	1	BY MR. SNELL:
2	did FTIR. I don't remember the others, but	2	Q The fact that's it's a strong indicator,
3	oxidation and degradation are related, but	3	though, that in and of itself means that
4	they're in terms of and there may be	4	there is some possibility that you will not
5	times that people use the word degradation to	5	see physical degradation, and there is a
6	consider all of these effects, but I'm	6	possibility as well that you will see it,
7	speaking specifically about oxidation as a	7	physical degradation, if you look at SEM,
8	chemical process, and degradation as a	8	correct?
9	physical one, and they're assessed by	9	MR. KUNTZ: Objection.
10	different techniques.	10	A Again, the literature tells us that you would
11		11	expect degradation. Is it unless you
12	And I don't remember all of the testing	12	
13	that Dr. Dunn did for the Huskey trial. I don't remember that.	13	actually see it, you can't prove you can't
14		14	guarantee that it's there, but you would
15	Q So if one does FTIR testing and sees that the surface is oxidized, that does not	15	certainly expect it. It's within a
16	·	16	reasonable degree of scientific certainty to
17	necessarily mean that the material is	17	expect that you would have degradation in
18	degraded, correct?	18	time if that surface is being oxidized.
19	A There are different tests to assess they	19	There are numerous papers that teach
20	could be degraded, but we would assess	20	about this, about polymers in general,
21	degradation using a different technique than	21	polymers that are susceptible to oxidative
22	FTIR. FTIR, as I said, is for chemical	21	attack showed signs of physical degradation.
23	oxidation, which is a chemical change. There	23	This was all worked out a number of years
24	may be degradation, but we would confirm that	24	ago.
25	with a technique such as SEM.	25	MR. SNELL: Move to strike.
25	Q So if a scientist has a positive FTIR finding	∠5	BY MR. SNELL:
	Page 43		Page 45
1	for oxidation on the surface, he would then	1	Q My question is this. It's straight forward.
2	need to confirm that with SEM in order to	2	The fact that you see chemical oxidation,
3	reasonably say with scientific certainty that	3	that does not mean that you would also see
4	there was degradation?	4	under SEM analysis physical degradation if
5	MR. KUNTZ: Objection.	5	you were to look at that particular time; is
6	A I would say that the literature teaches us	6	that correct?
7	that these processes are related, oxidation.	7	MR. KUNTZ: Objection. Asked
8	Chemical oxidation leads to physical	8	and answered. Calls for speculation, and is
9	degradation. And so if I see evidence of	9	an incomplete hypothetical. But go ahead.
10	oxidation, I would expect to see physical	10	A This is a speculative question. What I'm
11	degradation in time. To visibly see that	11	saying is, if there is oxidative changes, the
12	physical degradation, I would do the	12	body of literature teaches within a
13	technique such as SEM.	13	reasonable degree of scientific certainty
14	But if I see oxidation, I would certainly	14	that there will be at some time physical
15	expect based on published literature findings	15	degradation. That's what the literature is
16	that there would be degradation in time to	16	teaching us.
17	some extent.	17	BY MR. SNELL:
18	BY MR. SNELL:	18	Q You keep saying at some time there will be
19	Q Well, if you see chemical oxidation, it is	19	physical degradation. At what time will
20	not a guarantee that physical degradation has	20	there be physical degradation?
21	taken place, correct?	21	A As I've said in my previous testimony, it's
22	MR. KUNTZ: Objection.	22	unpredictable. And that's a problem for the
23	A I think I just answered that. It's a strong	23	design of the device, because it's subject to
24	indicator that there is also physical	24	changes that can happen that you can't
25	degradation.	25	predict the timing of these changes and what

12 (Pages 42 to 45)

the implications will be. Q Do you have an opinion as to what is the earliest point in time where there can be physical degradation of Ethicon's Prolene polypropylene used in TVT Abbrevo? A Again, that's a speculative question. I believe that upon implantation, the device will be colonized by adherent inflammatory cells. This is well-known in the literature, the foreign body reaction. Those cells will secrete species that oxidize it. The timing of lat these events can depend on a number of factors, the nature of the inflammatory response where it's implanted, the mechanical sresses in the environment, whether there is a bacterial infection. The timing can be highly variable. It can happen early or it can happen late. The point is that it's unpredictable. That's what I've been saying. Q Well, I would like to know what does the literature teach you about the earliest point in when you can say there is physical degradation of the Prolene polypropylene mesh? Page 47 I J don't want to rehash everything you talked about in Huskey. I Know you talked a about what was seen in two years and I believe five or seven years in a dog study and things like that. So with all of those principles that you've already testified about, let me just back up and re-ask it. A Okay. MR. KUNTZ: Objection. BY MR. SNELL: A Okay. MR. SYLL: Page 47 Page 47 I J don't want to rehash everything you talked about in Huskey. I Know you talked about that was seen in two years and I believe five or seven years in a dog study and things like that. So with all of those principles that you've already testified about, let me just back up and re-ask it. A Okay. MR. KUNTZ: Objection. WR. KUNTZ: Objection. MR. KUNTZ: Objection. MR. KUNTZ: Objection. A Jist starter menths and later. That's what Clave alos it st dus that in Clave, it says that — he notes that in Clave, it says that — he notes that in Clave, it says that — he notes that in Clave alone in John this in Clave and where in Clave it states that physical degradation or supplied. Page		Page 46		Page 48
2 Q Do you have an opinion as to what is the 3 earliest point in time where there can be 4 physical degradation of Ethicon's Prolene 5 polypropylene used in TVT Abbrevo? 6 A Again, that's a speculative question. I believe that upon implantation, the device 8 will be colonized by adherent inflammatory 9 cells. This is well-known in the literature, 10 the foreign body reaction. Those cells will secrete species that oxidize it. The timing of all these events can depend on a number of factors, the nature of the inflammatory response where it's implanted, the mechanical stresses in the environment, whether there is a bacterial infection. 1 The timing can be highly variable. It can happen early or it can happen late. The point is that it's unpredictable. That's what I've been saying. 21 Q Well, I would like to know what does the limit into when you can say there is physical degradation of the Prolene polypropylene mesh? 22	1	the implications will be	1	time periods of three months and later
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22 polypropylene mesh? 22 sutures?				
1 = 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				
24 Clave paper and the explants that were 24 so it's part of the documents I have				
25 studied in Clave, he recorded degradation in 25 reviewed.				

13 (Pages 46 to 49)

	Page 50		Page 52
1	Q At what point in time was physical	1	BY MR. SNELL:
2	degradation observed in that study?	2	Q My question was not what is he saying. My
3	A I can't remember. I would have to look at	3	question was to you, what limitations does
4	the document.	4	that place upon what one can draw from Clave
5	Q Okay. At a break, I would like for you to	5	due to the fact that only 32 out of 100
6	look at that document. And I will have the	6	explants were submitted for chemical testing?
7	same question for the vascular graft Prolene	7	A I don't see how it limits the finding that he
8	suture study, what is the earliest point in	8	sees changes. That's what he is reporting,
9	that study if at any point in time it showed	9	whether he sees it in 32 or 50, whether he
10	physical degradation?	10	looked at 32 or 100. I mean, you may be
11	A Again, I would have to look at it. I don't	11	implying that he was cherry-picking data, but
12	remember that level of detail.	12	I have no reason to believe that. This is a
13	Q Am I correct that although Clave reports	13	peer-reviewed journal.
14	there were 100 explanted samples, a smaller	14	I mean, he studied what he could study,
15	number were actually analyzed?	15	but it doesn't limit the finding that these
16	A What do you mean analyzed? I'm not sure what	16	changes happened. Whether he did 32 or 100,
17	you mean.	17	he still saw changes. So I don't understand
18	Q Let me ask you, how many explants were	18	how that limits that finding.
19	analyzed in the Clave study?	19	Q Well, he had 100 explants, and he only
20	A I would have to look at it. There were 100	20	subjected 32 to chemical analysis. We can
21	explants. I'm still not sure what you're	21	agree to that, right?
22	asking, though. I mean, there were 100	22	A That's what he states. But beyond that, I
23	explants.	23	don't
24 25	Q How many of those 100 explants were actually	24 25	Q And you don't know the methodology by which
<u> </u>	analyzed?	<u> </u>	he selected the particular 32 for chemical
	Page 51		Page 53
1	A Well, I think it depends on the method, so	1	analysis, correct?
2	they did a chemical analysis on 32 explants.	2	A Well, let me read it. I need to read this,
3	It doesn't necessarily say in the methods.	3	because I'm not quite following where you are
4	Q Why did Clave do less than one-third of the	4	going with this.
5	overall sample size for chemical analysis?	5	Okay. So he says I mean, he explains
6	A I don't know. I would have to look at this	6	himself. The samples were divided into four
7	to O. By only analyzing 22 out of 100 avalents for	7	groups. Because of the small sample size and
8 9	Q By only analyzing 32 out of 100 explants for	8 9	physical condition of the explanted
10	a chemical analysis, what limitations does		materials, extensive and complete chemical analysis was difficult, which I think most
11	that place upon the interpretation one can	10 11	*
12	draw from the Clave paper? A Well, what I believe Clave is saying is	12	would agree is true. And he has several groups listed here, four groups.
13	consistent with my opinions, that these	13	One of the fourth group is a control with
14	events can happen and can lead to problems	14	pristine implants, which he has a number of
15	and complications. He's not saying it	15	pristine implants listed. So he grouped one
16	happens all the time in every mesh at this	16	as degraded polypropylene that he analyzed by
17	particular time.	17	SEM.
18	He is saying that these meshes change,	18	Group two is a group of nondegraded
19	which is consistent, which is my opinion in	19	explants, which again looks like
20	this case, that the meshes change, and that	20	polypropylene mesh. And then the fourth
21	introduces an extra level of risk because	21	group of PET explants. That's what he says
22	these changes make the meshes make their	22	he did. And he says it was difficult. He
23	behavior unpredictable. That is what he is	23	probably didn't have much material to work
24	saying.	24	with, but these are explants. This isn't a
	MR. SNELL: Move to strike.	25	clinical trial. These are explants, so that

14 (Pages 50 to 53)

	Page 54		Page 56
1	is what he had to work with.	1	it as, wow, one-third were degraded, that's a
2	Q But do you know then the methodology by which	2	lot. That's how I look at it.
3	he determined the cut point for whether it	3	Q Regardless of how you want to characterize
4	was too difficult or not to do SEM analysis?	4	it, let's see if we can agree to this.
5	A He doesn't provide more detail, but this is	5	Dr. Guelcher, we can both agree that
6	what I understand that he did.	6	Dr. Clave reported that the rate of
7	Q So we have no way of knowing what chemical	7	degradation in the polypropylene monofilament
8	analysis would have shown for those 68	8	was one-third or 33.33 percent, correct?
9	explants that were not subjected to chemical	9	A That's what he reported. But to try to
10	analysis; is that fair?	10	construe that that is a good number is beyond
11	A Say that again. I didn't catch it.	11	my understanding. That's what he reported.
12	Q Sure.	12	He reported that one-third were degraded.
13	We do not know what, if anything, would	13	MR. SNELL: Move to strike. I'm
14	have been shown for the 68 other explants	14	just looking for a yes or no.
15	that were not subjected to chemical analysis	15	BY MR. SNELL:
16	because the chemical analyses were not done;	16	Q If we can agree to this basic fact. How you
17	is that fair?	17	characterize it, I know what position you're
18	A We don't know. He didn't report it, for	18	coming from. All right.
19	reasons that I'm not entirely sure.	19	In the Clave paper for the polypropylene
20	Q And in Clave's paper, am I correct that not	20	monofilament, the rate of degradation seen
21	all of the polypropylene explants were even	21	was one out of three or 33.33 precent,
22	had physical degradation?	22	correct?
23	A Yes. But I talked about this earlier, Clave	23	A That's what's in the table.
24	is not trying to report the incidents of	24	Q Fair enough.
25	strike that. He's not trying to report	25	And you have your interpretation of that?
	Page 55		Page 57
1	frequency. He is saying that he observed it.	1	A I do.
2	With what he had, with what he could test, he	2	Q And let me ask you, if more likely than not
3	observed evidence. He doesn't say he	3	it's 51 percent or higher, you can't look at
4	observed it in every sample, but he did	4	the Clave paper and say it's more likely than
5	observe it. That's what he is saying. So he	5	not that there would be degradation to
6	did not observe it in every sample, but we've	6	polypropylene monofilament mesh, correct?
7	talked about this.	7	MR. KUNTZ: Objection. You can
8	Q Dr. Clave did report the rate of degradation	8	answer.
9	that he saw in the samples that he actually	9	A If I were a patient looking at that number, I
10	did analyze, correct?	10	would be concerned.
11	A He did report that number but	11	MR. SNELL: Move to strike.
12	Q So for polypropylene monofilament at the	12	Nonresponsive.
13	table at the top of Page 266, do you see	13	BY MR. SNELL:
14	that?	14	Q When you look the Clave paper, you can't say
15	A I see that number. I know what you're	15	it's more likely than not that there was
16	saying.	16	degradation to the polypropylene monofilament
17	Q And you understand the Prolene polypropylene	17	mesh, correct?
18	mesh in the TVT Abbrevo to be a monofilament	18	MR. KUNTZ: Objection.
19	polypropylene?	19	A I don't even know how to answer that
20	A Yes.	20	question. I mean, it's he reported 33
21	Q And what Clave found was that only one-third	21	percent. I will agree that he reported that
22	of that sample of polypropylene monofilament	22	in this table, in table two, he reports or
23	that he actually looked at was degraded,	23	figure two, he reports that 33 percent were
24	correct?	24	degraded. Beyond that, I can't that's
25	A I look at it a little differently. I look at	25	what he says.

15 (Pages 54 to 57)

	Page 58		Page 60
1	BY MR. SNELL:	1	That's what I'm saying. Unpredictable means
2	Q So you would agree that Dr. Clave's paper in	2	you can't predict, and that's a problem.
3	this table and report, that it's more likely	3	That's why the design is flawed is because
4	than not that the mesh was actually not found	4	you can't predict. The changes can happen,
5	to be degraded, correct?	5	and you can't predict when or the
6	A I cannot answer that question. That doesn't	6	implications of those changes.
7	make any sense. I mean, this is what he	7	My simple point is that Clave sees those
8	reported. To try to construe that that's	8	events and reports them, but this is not a
9	what he reported and what he tested. To try	9	study designed to investigate the number of
10	to construe more out of this, this wasn't a	10	meshes that got that were degraded.
11	controlled study where he was trying to	11	That's not what he is saying. He is
12	measure race of degradation. He made	12	observing he is reporting an observation.
13	observations and he reported a number, this	13	I think you're misinterpreting. You're
14	percentage that I saw to be degraded.	14	trying to put me in a position to
15	He was not aiming to estimate some he	15	misinterpret Clave, and I can't do that. I
16	is just reporting. This is the way I read	16	can only report on what I see.
17	this paper. So I can't answer this question	17	BY MR. SNELL:
18	that it's more likely than not on anything.	18	Q So you can only report that for the samples
19	That's just the number he provides.	19	that Clave did decide to analyze for
20	Q So the Clave paper we can agree does not	20	degradation, it was 33.33 percent for the
21	stand for the proposition that it's more	21	polypropylene monofilament, and to try to
22	likely than not that polypropylene	22	take that number and extrapolate it is not
23	monofilament is degraded?	23	something you're willing to do?
24	MR. KUNTZ: Objection.	24	MR. KUNTZ: Objection.
25	A I can't agree to this line of questioning.	25	A When have I done that in trial testimony?
	Dogo FO		
	Page 59		Page 61
1		1	
1 2	This is why can't we not just agree that	1 2	You've seen my depositions. MR. SNELL: Move to strike.
			You've seen my depositions.
2	This is why can't we not just agree that I agree this is what he reported. And	2	You've seen my depositions. MR. SNELL: Move to strike.
2 3	This is why can't we not just agree that I agree this is what he reported. And beyond that, I'm not going to agree to any	2	You've seen my depositions. MR. SNELL: Move to strike. BY MR. SNELL:
2 3 4	This is why can't we not just agree that I agree this is what he reported. And beyond that, I'm not going to agree to any other interpretation of that number. That's	2 3 4	You've seen my depositions. MR. SNELL: Move to strike. BY MR. SNELL: Q We are going to be here all day. I'm not
2 3 4 5	This is why can't we not just agree that I agree this is what he reported. And beyond that, I'm not going to agree to any other interpretation of that number. That's what he reports. It's an observation saying that this can happen, which is what I've been saying in my trial and deposition testimony,	2 3 4 5	You've seen my depositions. MR. SNELL: Move to strike. BY MR. SNELL: Q We are going to be here all day. I'm not asking about when did I see you doing
2 3 4 5 6 7 8	This is why can't we not just agree that I agree this is what he reported. And beyond that, I'm not going to agree to any other interpretation of that number. That's what he reports. It's an observation saying that this can happen, which is what I've been saying in my trial and deposition testimony, that these events can happen and Clave	2 3 4 5 6 7 8	You've seen my depositions. MR. SNELL: Move to strike. BY MR. SNELL: Q We are going to be here all day. I'm not asking about when did I see you doing something. I'm really not. A I just feel like you're covering old ground that I've been over so many times, and you're
2 3 4 5 6 7 8 9	This is why can't we not just agree that I agree this is what he reported. And beyond that, I'm not going to agree to any other interpretation of that number. That's what he reports. It's an observation saying that this can happen, which is what I've been saying in my trial and deposition testimony, that these events can happen and Clave observed it. That's what it says.	2 3 4 5 6 7 8	You've seen my depositions. MR. SNELL: Move to strike. BY MR. SNELL: Q We are going to be here all day. I'm not asking about when did I see you doing something. I'm really not. A I just feel like you're covering old ground that I've been over so many times, and you're trying to get me to misrepresent a paper that
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16 (Pages 58 to 61)

	Page 62		Page 64
1	I just feel like I have been very clear about	1	there is no case specific depositions on
2	what I think about this paper. And I'm just	2	there.
3	saying that it is consistent with my	3	MR. SNELL: Well, that is what I
4	testimony that these events can happen.	4	was going to say.
5	That's what I am saying. That's what I have	5	BY MR. SNELL:
6	always been saying.	6	Q So, Dr. Guelcher, I looked at your reliance
7	Q I just want to get an answer to my question.	7	list. It's on the thumb drive. And I didn't
8	You interpret Clave as being consistent	8	see any case specific depositions,
9	with your opinion in that it can happen. And	9	particularly from Mrs. Perry's case. Is that
10	Clave observed it in 33.33 percent, correct?	10	consistent or inconsistent with your
11	A Yes, he observed it in 33 percent, that's	11	knowledge?
12	fine.	12	A I have it's consistent with my knowledge,
13	Q But you not take Clave and extrapolate Clave	13	yeah.
14	to say that a certain rate of degradation	14	Q You're not relying on any case specific
15	will be seen in the mesh samples? Yes or no.	15	depositions in the Perry case for your
16	MR. KUNTZ: Asked and answered.	16	opinions are you, sir?
17	Eight times.	17	A I am not.
18	A I've not done that and I'm not doing that	18	Q All right. Thank you.
19	now.	19	A Okay.
20	BY MR. SNELL:	20	Q Earlier we were talking about some testing.
21	Q Okay. That's all I wanted to know was is	21	And you didn't do any SEM testing on
22	that something you would do or would not do.	22	Mrs. Perry's explant, correct?
23	A Well, where you ended up with the question, I	23	A No, I did not.
24	was fine with it. I'm not trying to be	24	Q Did you have anybody else do any testing of
25	difficult. I'm sorry.	25	Mrs. Perry's explant on your behalf?
	Page 63		Page 65
1	MR. SNELL: All right. Let's	1	A I did not.
2	take a break.	2	Q Okay. You didn't do any FTIR testing on
3	(A brief recess was taken from	3	Mrs. Perry's explant, correct?
4	10:40 to 10:50 a.m.)	4	A I did not.
5	BY MR. SNELL:	5	Q Did you do any GPC testing on Mrs. Perry's
6	Q Doctor, you didn't look at Mrs. Perry's	6	explant?
7	medical records, correct?	7	A No. The only explant I received was in the
8	A I did not look at her records.	8	form of sections of the slides of tissue, so
9	Q Did you look at any of the depositions taken	9	it's I didn't do any of this type of
10	in Mrs. Perry's case, hers or any of her	10	testing on that material.
11	doctors or family members?	11	Q You did not do XPS testing on Mrs. Perry's
12	A I looked at some depositions, but I can't	12	mesh, correct?
13	remember exactly those I don't know.	13	A That's correct.
14	Q Are you certain that they were depositions in	14	Q You did not do DSC testing on Mrs. Perry's
15	the Perry case or could they have been from	15	mesh, correct?
16	some other matter?	16	A No.
17	A It could have been. There has been so many	17	Q You did not do EDX testing on Mrs. Perry's
18	cases, it's hard for me to keep all of the	18	mesh; is that correct?
19	documents straight.	19	A That's correct.
20	Q I'm looking at your reliance list, and I gave	20	Q Are there any tests besides SEM, FTIR, GPC,
	you this back.	21	XPS, DSC and EDX that someone can do to look
21			for aither about all an atments and
22	A The reliance list?	22	for either chemical or structural
22 23	Q Your list of materials on there that you	23	degradation?
22			

17 (Pages 62 to 65)

	Page 66		Page 68
1	don't believe, but he has a microscopic	1	manuscript.
2	method for evaluating degradation of the mesh	2	Q As you sit here today, is it correct, sir,
3	by microscopy.	3	that you do not know the particular patients
4	Q Dr. Iakovlev is a pathologist as you	4	for whom those slides were made that are
5	understand it?	5	going to be the subject of this manuscript?
6	A He is a pathologist at a hospital in Toronto.	6	A That is correct. I do not know their
7	Q And Dr. Iakovlev is not an expert in this	7	identity.
8	case to your knowledge; is that correct?	8	Q Okay. Actually, some slides from Mrs. Perry
9	A To my knowledge. I've not discussed this	9	were brought to the deposition today,
10	case with Dr. Iakovley.	10	correct?
11	Q Do you know if Dr. Iakovlev has looked at	11	A That's correct.
12	Mrs. Perry's mesh or slides?	12	Q Have you looked at those slides?
13	MR. KUNTZ: Objection.	13	A I looked at them visually, but I did not look
14	A Not to my knowledge.	14	at them under the microscope.
15	BY MR. SNELL:	15	Q Okay. Now, the Perry slides that you looked
16	Q Do you know if Dr. Iakovlev's microscopic	16	at visually, how did you come to obtain
17	method for evaluating mesh has been analyzed	17	those?
18	by any of the pathology medical societies,	18	A Through plaintiff's counsel.
19	like the American Association of Surgical	19	Q You didn't get those through from
20	Pathologists or the American College of	20	Dr. Iakovlev?
21	Pathology?	21	A No, I did not. Plaintiff's counsel.
22	A I don't know the answer to that. But we are	22	Q And you have not sent Mrs. Perry's slides to
23	preparing a manuscript on explaining mesh	23	Dr. Iakovlev, correct?
24	that will be submitted soon. And I'm a	24	A I received the slides from Plaintiff's
25	co-author on that manuscript.	25	counsel, and they have been in my possession
	Page 67		Page 69
1	Q Does this manuscript concern Mrs. Perry's	1	since.
2	explant to your knowledge?	2	Q Okay. When did you receive those slides that
3	A I am not aware of Dr. Iakovlev strike	3	are particular to Mrs. Perry?
4	that. From my perspective, the patients are	4	A A few weeks ago maybe. I don't remember
5	de-identified. I don't know the identity of	5	exactly.
6	any patients in that study. What	6	Q What is this myeloperoxidase stain that you
7	Dr. Iakovlev knows, I don't know.	7	referenced earlier?
8	Q And were these explanted meshes received by	8	A It's myeloperoxidase. It's spelled
9	you or Vanderbilt or were they received by	9	M-Y-E-L-O-P-E-R-O-X-I-D-A-S-E.
10	Dr. Iakovlev or someone else?	10	Q And what is the purpose of the
11	A They were all received by Dr. Iakovlev from	11	myeloperoxidase stain?
12	varying sources. And all of those details,	12	A So myeloperoxidase is an enzyme that converts
13	he knows. I did not handle the specific	13	hydrogen peroxide and other substrates to
14	materials. I was never involved in that.	14	hydroxl radicals and other forms of reactive
15	Q For this testing, who did the testing that is	15	oxygen species. And so if we see a stain
16	going to be the subject of this manuscript?	16	that is positive for myeloperoxidase, that
17	A So Dr. Iakovlev did the testing. My	17	tells us that the inflammatory cells are
18	contribution was suggesting disdain for	18	secreting reactive oxygen species, that the
19	myeloperoxidase, which is a marker for	19	mesh is being exposed to the reactive oxygen
20	reactive oxygen. And that information is	20	species and would therefore be a marker of
21	concluded and discussed in the manuscript.	21	this initiation of events of oxidation and
	And I have assisted Dr. Iakovlev with	22	degradation. That's the purpose of the
22			
22 23	revising and editing the manuscript.	23	stain.
22		23 24 25	

18 (Pages 66 to 69)

this myeloperoxidase stain; is that correct? A That's my understanding. Q So as I understand it, the myeloperoxidase stain 5 A You can call it MPO. G Thank you. That makes it a lot easier. The MPO stain is a stain that one can do to look for reactive oxygen? A That's correct. I published two papers on this in my work at Vanderbilt. So it's a routine essay. Q And reactive oxygen is what these inflammatory cells secrete or can secrete; is inflammatory cells secrete or can secrete; inflammatory cells secrete or can secrete; is inflammatory cells secrete or can secrete; inflammatory cells secrete or can sec	72
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A That's correct. I published two papers on this in my work at Vanderbilt. So it's a 10 this in my work at Vanderbilt. So it's a 10 this in my work at Vanderbilt. So it's a 10 have those slides stained for MPO, correct? 11 A It's a complicated question how these samples are handled, whether or not they're in the right form that it can be done. I would think we would need the blocks to cut new slides. I don't know what material is available. I would say in theory it could be done, but I don't know how practical that is. I don't know the history of the explants. 14 I don't know the history of the explants. 15 I don't know the history of the explants. 16 I don't know the history of the explants. 17 I don't know the history of the explants. 19 I don't know the history of the explants. 19 I don't know the history of the explants. 19 I don't know the history of the explants. 19 I don't know the history of the explants. 19 I don't know the history of the explants. 19 I don't know the history of the explants. 19 I don't know the history of the explants. 19 I don't know the history of the explants. 19 I don't know the history of the explants. 19 I don't know the history of the explants. 20 I don't know the history of the explants. 20 I don't know the history of the explants. 21 I don't know the history of the explants. 21 I don't know the history of the explants. 22 I don't know the history of the explants. 23 I don't know the history of the explants. 24 I would not be the one looking at the slides under the microscope if an MPO stain was done in any event? 24 I was done in any event? 25 I was done in any event? 25 I was done in any event? 26 I was done in any event? 27 I was done in any event? 28 I was done in any event? 29 I was done in any event? 20 I was done in any event? 20 I was done in any event? 20 I was done in any event? 21 I was done in any event? 22 I was done in any event? 22 I was done in any event? 23 I was done in any ev	
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staining in the ones that he's stained. 13 A To confirm it. I need to be very clear what	
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scientific certainty, I would expect to see 15 scientific certainty, my work with	
myeloperoxidase, but we did not those 16 Dr. Iakovlev, my reading of the literature, I 17 would fully expect to see positive stein from	
stains, those slides to my knowledge have not would fully expect to see positive stain from	
been stained for MPO, and so I could not assess that. 18 myeloperoxidase. That has not been visibly confirmed in a section because the slides	
20 Q Is it fair to say you could not assess in the 20 have not stained for that enzyme.	
21 Perry case MPO's presence at the mesh; is 21 Q What is the literature that you are	
that correct? 22 what is the interactive that you are 22 referencing with regard to your opinion that	
23 A I don't think I like the words could not. 23 you would expect the MPO stain to be positive	e
They could be stained. This work could be 24 if it was done in Mrs. Perry's case?	·
done, but that's a decision for plaintiff's 25 A The paper that comes to mind would be a	

19 (Pages 70 to 73)

	Page 74		Page 76
1	review paper by Professor Jim Anderson at	1	Q How large of a cohort is this?
2	Case Western from 2008 where he cites a very	2	A 130 patients, explants from 130 patients.
3	large number of papers in this review.	3	Q And this is a cohort for whom you do not know
4	And he teaches that upon implantation,	4	which patients are particularly involved?
5	the surface is colonized by these monocytes,	5	A I am blind to patient identity.
6	inflammatory cells, that differentiate in the	6	Q Okay. Would it be fair to say you do not
7	macrophages, foreign body giant cells, and	7	know which manufacturer's meshes are involved
8	become activated when they adhere to that	8	for whichever particular patient in that
9	surface and secrete reactive oxygen species,	9	study?
10	such as myeloperoxidase or they produce.	10	A I believe that in the manuscript,
11	Q This work by Dr. Iakovlev, has it been	11	Dr. Iakovlev mentions some of the devices,
12	published anywhere that you have seen, in a	12	but I don't know which device went in which
13	peer-reviewed journal?	13	patient. And I don't know if Dr. Iakovlev
14	A It's not been published. We're preparing to	14	has that information.
15	submit it, the manuscript. It's not been	15	Q As you sit here, you do not personally have
16	published yet, though. It's still a	16	knowledge about what device went into which
17	confidential work product that will be	17	patient?
18	submitted.	18	A I do not.
19	Q Do you have a copy of the manuscript on the	19	Q As you sit here, you do not personally know
20	thumb drive?	20	which particular manufacturer's devices were
21	A No. It's a confidential work product with	21	the subject of the 130 patients?
22	Dr. Iakovlev, so we have to maintain strict	22	A I believe I have that information. It may be
23	confidentiality when we submit to the	23	in the manuscript. I just can't remember. I
24	journals so we don't compromise the review	24	don't remember. That information may be in
25	process.	25	the manuscript, but certainly I don't know
	Page 75		Page 77
1	Q Do you know the rate at which the MPO	1	which device was with which patient. I would
2	standing was positive in the samples that	2	not know that because I don't know the
3	Dr. Iakovlev did?	3	patients.
4	A 3371 , T ,1 * 1		
	A When you say rate, I think you mean	4	Q You don't have personal knowledge such that
5	frequency?	5	Q You don't have personal knowledge such that you have confirmed that a particular
5 6	frequency? Q Sure.	5 6	Q You don't have personal knowledge such that you have confirmed that a particular manufacturer's device was the subject of the
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20 (Pages 74 to 77)

	Page 78		Page 80
1	because it's not been published yet, and	1	and the properties change very dramatically.
2	we're not disclosing it, so	2	But degradation can occur prior to induction,
3	Q Okay.	3	and it certainly can occur after induction,
4	A You're asking me about my experience with	4	so the two processes are related.
5	mesh and I'm telling you. That's my	5	The mechanical stresses can certainly
6	understanding.	6	impact this as well. That's known as
7	Q Fair enough.	7	environmental stress cracking. So they are a
8	You're not relying on that manuscript in	8	factor, so you can't separate the two. The
9	the 130-patient analysis for your opinions in	9	mechanical stresses and the chemical stresses
10	this case, in the Perry case?	10	are interrelated.
11	A Yes, I would say those findings confirm my	11	Q You've not seen any embrittlement of
12	opinions, but I am not relying on them	12	Mrs. Perry's mesh, correct?
13	because that manuscript is still a work in	13	A I have not tested for it and have not seen
14	progress.	14	it.
15	Q So when the inflammatory cell attaches to the	15	Q You've not seen any cracking of Mrs. Perry's
16	mesh or to a foreign body, MPO is one of the	16	mesh, correct?
17	substances it can release?	17	A Correct. I haven't tested for it and seen
18	A Well, I would say that MPO is an enzyme in	18	it.
19	the cell that catalyzes the reaction of	19	Q You have not seen any molecular weight loss
20	substrates, such as peroxides, to form,	20	from Mrs. Perry's mesh, correct?
21	reactive oxygen species such as, you know,	21	A No. I've not tested for that and seen it.
22	hydroxl radicals, superoxide. There is a	22	Q Besides the macrophages, are there any other
23	very large number of these reactive oxygen	23	cells that you will plan to testify can
24	species, but MPO is an enzyme that generates	24	release these reactive oxygen species?
25	those reactive oxygen species.	25	A Well, Dr. Anderson teaches that monocytes,
	Page 79		Page 81
1	Q It's your opinion that the reactive oxygen	1	which are very small mononuclear cells,
2	species produce compounds, chemicals, which	2	colonize the implant, and then those cells
3	has an affect on the mesh?	3	and they adhere to the implant. And when
4	A So the reactive oxygen species do impact the	4	they attach or adhere to the surface of the
5	mesh. They through this oxidation	5	implant, they become activated. They can
6	chemistry of polypropylene, the tertiary	6	differentiate to become macrophages or
7	carbon hydrogen bond is subject to attack,	7	macrophages can fuse to form foreign body
8	and those radicals will attack that bond and	8	giant cells.
9	oxidize the polypropylene.	9	And these cells all come from a common
10	Q If the radicals don't attack the bond, does	10	lineage, so they're all inflammatory cells.
11	the polypropylene get oxidized?	11	So when they're adhered, they're activated to
12	A It may be other mechanisms. The most	12	secrete ROS. Other types of cells, such as
13	well-known is this radical attack.	13	neutrophils, which is commonly seen during
14	Q Are you going to come in and testify that	14	acute inflammation or infection, also secrete
15	there are other methods by which the	15	ROS. So there are other cell populations.
			D 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
16	polypropylene gets degraded besides this, you	16	Really just many, many types of cells secrete
17	polypropylene gets degraded besides this, you know, attacking the bond that you've talked	17	ROS. But in my previous testimony, I was
17 18	polypropylene gets degraded besides this, you know, attacking the bond that you've talked about? I don't see it here in your summary	17 18	ROS. But in my previous testimony, I was focusing specifically about these adherent
17 18 19	polypropylene gets degraded besides this, you know, attacking the bond that you've talked about? I don't see it here in your summary of opinions.	17 18 19	ROS. But in my previous testimony, I was focusing specifically about these adherent macrophages in giant cells.
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17 18 19 20 21 22 23	polypropylene gets degraded besides this, you know, attacking the bond that you've talked about? I don't see it here in your summary of opinions. A So in my summary of opinions, I discussed the interactions between oxidation and degradation. And my point is that oxidation as we're saying is a very early event. It	17 18 19 20 21 22 23	ROS. But in my previous testimony, I was focusing specifically about these adherent macrophages in giant cells. Q It's fair to say you're going to focus on the adherent macrophages in giant cells in the Perry case? A Yes.
17 18 19 20 21 22	polypropylene gets degraded besides this, you know, attacking the bond that you've talked about? I don't see it here in your summary of opinions. A So in my summary of opinions, I discussed the interactions between oxidation and degradation. And my point is that oxidation	17 18 19 20 21 22	ROS. But in my previous testimony, I was focusing specifically about these adherent macrophages in giant cells. Q It's fair to say you're going to focus on the adherent macrophages in giant cells in the Perry case?

21 (Pages 78 to 81)

	Page 82		Page 84
1	A So the signaling is very complex and it's	1	Academy, and his seminal work is in this area
2	reviewed in Dr. Anderson and it's just	2	of foreign body reaction. And in this paper,
3	part of the foreign body reaction. When you	3	he is saying that the cells adhere and become
4	implant a foreign body, many different types	4	activated. And I know that there is a fair
5	of cells infiltrate that site of injury, and	5	amount of scientific research aimed at this
6	there are various chemical signaling factors	6	idea of inactivating macrophages. I'm aware
7	that are involved. It's just very complex.	7	of this.
8	Q Well, let's not go down that road. I was	8	But, again, to my knowledge, the teaching
9	trying to get to a simplistic step-by-step	9	in the field is that they are activated. The
10	process.	10	work I've done with Dr. Iakovlev is saying
11	So the macrophages are signaled to the	11	that when we see these cells, we see
12	site of the mesh or wherever there would be a	12	myeloperoxidase when we stain for it. So
13	foreign body?	13	that's why I'm expressing the opinion with a
14	A I would say that monocytes are recruited due	14	reasonable degree of scientific certainty
15	to the injury, and that mechanism is very	15	that these cells are activated and secrete
16		16	
17	complex. But they go to the site of injury,	17	ROS when they are attached, when they adhere
18	and they adhere to the foreign body.		to the foreign body.
19	Q Okay. I guess the question I want to ask is,	18	Q Did you look for literature that was contrary
	monocytes in the foreign body giant cells,	19	to your opinion that these cells remain
20	it's correct that they can persist at the	20	activated?
21	site of a foreign body for years, correct?	21	A I'm aware of work in this area just through
22	A So Dr. Anderson teaches in that review that	22	my work that I do. I can't think of a
23	they're present	23	specific paper right now. If you have one
24	Q Can you answer my question yes or no and then	24	you want me to look at, I can. I'm just
25	the basis after?	25	expressing my general understanding in the
	Page 83		Page 85
1	A Okay. It's just the way you're phrasing it,	1	field without any documents in front of me.
2	I don't necessarily want to say yes or	2	Q You're aware of the belief in the field that
3	that's the only problem.	3	these inflammatory cells can become
4	Q All right. Fair enough.	4	quiescent, and they do not necessarily remain
5	A I want to answer. I just want to make sure	5	activated at the site of the foreign body?
6	that there is a clean record of what I'm	6	A I don't there are ideas that I don't
7	saying.	7	know that quiescent I think is a strong
8	Q All right. So macrophages formed by giant	8	word. Maybe there are varying levels of
9	cells can persist at the site of the mesh or	9	activity, but I don't know that I've seen
10	foreign body; is that correct?	10	convincing proof that they are just
11	A Yes, they are there again, in the Anderson	11	completely quiescent. Again, if you would
12	paper, they are there for the lifetime of the	12	like me to look at a paper, I will look at
13	device. They're persisting.	13	one, but this is my understanding.
14	Q And when you say the Anderson paper, is that	14	Q What are lysosomal constituents?
15	the one you identified earlier on the record,	15	A Can you put some context to that? I'm not
16	sir?	16	just to give me a phrase. Lysosomal
17	A Yes, sir.	17	constituents, I mean, what's the context of
18	Q Okay. Thank you.	18	it?
19	Now, isn't it true, Doctor, that those	19	Q With regard to foreign body giant cells,
20	macrophages in foreign body cells that	20	whether they remain activated releasing their
21	persist at the site of the foreign body can	21	lysosomal constituents?
22	become quiescent?	22	A I'm just not I could look at something.
23	A I've seen this idea proposed. Again, I'm	23	It's hard for me to answer that just in the
24	relying on Dr. Anderson's 2008 review. And	24	way that question is phrased. I would have
25	Dr. Anderson is a member of the National	25	to look at what you're referring to, because

22 (Pages 82 to 85)

	Page 86		Page 88
1	I am just not sure what you mean.	1	A I understand.
2	Q Did you research the question of whether	2	Q In the paper by Jim Anderson, does he state
3	inflammatory cells become quiescent or	3	that those macrophages in foreign body cells
4	deactivated at the site of a foreign body?	4	continue to release the substances at the
5	A I don't remember specifically doing that for	5	site of the foreign body as years continue to
6	this particular litigation.	6	progress and they remain activated? Is that
7	Q Are there any books in your field considered	7	conclusively stated in the paper?
8	authoritative or important to these general	8	A So I'd like to answer that by stating what
9	principles of foreign body reaction?	9	Dr. Anderson does say in that paper. He says
10	A I don't know. There is lots of I mean,	10	that the cells become activated, and that the
11	I've got a book on biomaterials that has	11	foreign body reaction is present throughout
12	Professor David Williams has just released a	12	the lifetime of the device. And then he
13	book on biomaterials. There is a book	13	qualifies that as, albeit, in some cases at a
14	Biomaterials Science by four very well-known	14	low level.
15	senior scientists that discuss these ideas.	15	So what he is saying, and then what his
16	You know, these are all important books.	16	point is, is that as long as the device is
17	Q Let me ask you this. Is there any way to	17	there, this foreign reaction body is ongoing,
18	test to know whether the cells are remaining	18	and that these factors need to be considered
19	activated?	19	in the design of the medical device. That's
20	A Well, that's the myeloperoxidase stain. When	20	what he says.
21	I see a positive stain for MPO, that's	21	Q Okay. So Dr. Anderson does not state that if
22	staining for that enzyme, and that's telling	22	the cells are there, they are going to be
23	us that the cells are generating ROS. That's	23	activated and producing these substances?
24	how you do it.	24	A I would say it's implied. It doesn't
25	Q Is there any other test that you can do that	25	necessarily specifically state that. And I
	Page 87		Page 89
_	_		
1	would actually show those substances released	1	would be happy to read it from the paper, but
2	by the ROS?	2	it's very strongly implied that that's what's
3	A It's more difficult to do because they are	3	happening in the way that it is stated.
4	such small molecules. The myeloperoxidase	4	THE WITNESS: I have to go to
5	is just a very you know, it's a relatively	5	the bathroom if you don't mind.
6	straight forward stain to do.	6	MR. SNELL: Let's take a break.
7	Q Do you know if the MPO stain is recognized by	7	(A lunch recess is taken from
8	the American College of Pathology as a proper	8	12:00 to 12:50 p.m.)
9	stain for assessing the release of that	9	THE COURT: Let's take a break.
10	substance by ROS?	10	BY MR. SNELL:
11	A I don't know. We looked at you know, I	11	Q Doctor, we are going to mark the Perry
12	published this, so it's been peer-reviewed.	12	pathology slides that you have in your
13	It was accepted as a marker of presence of	13	possession as Exhibit No. 2.
14	oxidative conditions.	14	(Deposition Exhibit No. 2 is
15	Q Does Dr. Williams' paper that you referenced	15	marked for identification.)
16	state with certainty that those macrophages	16	BY MR. SNELL:
17	of foreign body giant cells continue to	17	Q And I will hand you Exhibit 2. Just confirm
18	remain activated and release substances on	18	for the record that those are the slides,
19	the surface of the biomaterial?	19	sir.
20	A I think you're getting papers confused. I	20	A Yes, these are the slides I was presented.
21	was referring to the Anderson 2008 paper.	21	Q It looks like there is three different sets,
22	Q Okay. I'm sorry. So let me just ask a	22	each of them wrapped in bubble wrap?
23	better question. Anytime you need to the	23	A Yes.
24	correct me, let me know. I get these things	24	Q Am I correct, sir, that you're not relying on
25	confused.	25	those pathology slides for your opinions?

23 (Pages 86 to 89)

	Page 90		Page 92
1	A That's correct.	1	It's not going to work on a histological
2	Q Do you know what type of inflammatory cells,	2	section. You would need mesh from the
3	if any, are present in Mrs. Perry's mesh?	3	patient before it's been processed for
4	A I don't know. I didn't look at the slides	4	histology to do those measurements.
5	under a microscope.	5	Q You said that was nano
6	Q You therefore would not know how many of any	6	A Nanoindentation could measure the brittleness
7	inflammatory cells, if they are present, were	7	of the surface degraded layer.
8	actually there, correct?	8	Q Is that a particular type of test,
9	A That's correct.	9	nanoindentation?
10	Q When we were talking about the inflammatory	10	A It is.
11	cells, just so we're on the same page, I'm	11	Q Is it separate and apart from some of the
12	referring to the macrophages in foreign body	12	other testing that we've discussed?
13	giant cells?	13	A It is. It is mechanical testing at a very
14	A Yes.	14	small scale. I've done testing like this
15	Q Okay. So when we say chronic inflammatory	15	with a collaborator at Vanderbilt where we
16	cells	16	probed the surface with a cantilever beam,
17	A Yes.	17	and we measure the response and the
18	Q are we talking about macrophages in the	18	mechanical force. You can measure an elastic
19	foreign body giant cells?	19	modulus doing this.
20	A Yes.	20	Q You have not done any of this
21 22	Q Okay. Do you know whether there were any	21 22	nanoindentation testing on Mrs. Perry's mesh, correct?
23	chronic inflammatory cells present in	23	A That's correct.
24	Mrs. Perry's vaginal tissue before her surgeries, one of which included mesh?	24	Q Have you seen any photographs of Mrs. Perry's
25	A I'm not aware of that information.	25	mesh that showed cracking?
23	Page 91	23	Page 93
1	_		
1 2	Q Did you attempt to look at any of the	1 2	A I've not seen any photographs of her mesh.
3	pathology reports in Mrs. Perry's case? A No, I did not review those reports.	3	Q Earlier you were talking about the bonding that can occur leading to degradation of the
4	Q Have you attempted to measure any of the	4	particular atom. I don't recall if it was
5	reactive oxygen species in Mrs. Perry?	5	carbon or hydrogen.
6	A We talked about this earlier. I didn't do	6	A You are referring to oxidation and a free
7	that.	7	radical attack on a tertiary carbon hydrogen
8	Q Have you attempted to do any mechanical	8	bond?
9	testing of Mrs. Perry's mesh?	9	Q Yes, sir.
10	A No.	10	A Yeah.
11	Q Are you aware of any testing done on	11	Q So for oxidation, is that oxygen which comes
12	Mrs. Perry's mesh to determine whether it	12	and bonds with carbon or the other way
13	became tougher after implantation?	13	around?
14	A I'm not aware of any other testing on her	14	A The details of the reaction are very complex.
15	mesh.	15	But, essentially, it's a radical attack, a
16	Q And you would not have done such testing to	16	hydroxl radical or oxygen radical can attack
17	determine whether it became tougher, correct?	17	that bond. The chemistry is very
18	A Seems like I'm not sure what you mean by	18	complicated.
19	the mesh became tougher. I mean, it seems	19	Q What is the difference between an oxygen
20	like it would be difficult to do.	20	molecule and an oxygen radical?
21	Q You could test to determine whether the mesh	21 22	A Well, it's just the nature of the chemical
22 23	became embrittled in Mrs. Perry, correct?	23	reaction. In the body and in our in vitro
24	A Test the outer layer, that could be done by a nanoindentation. But, again, you need an	24	testing I can speak specifically from our in vitro testing, the solution that we
25	appropriate amount of mesh in the right form.	25	created generated hydroxl radicals, and those
ر ک	appropriate amount of mesh in the fight form.	_ L J	created generated frydroxi radicals, and mose

24 (Pages 90 to 93)

	Page 94		Page 96
1	hydroxl radicals attacked that carbon	1	carbon-oxygen bonds that we can detect by
2	hydrogen tertiary bond tertiary carbon	2	XPS.
3	hydrogen bond.	3	Q Have you attempted to look for the presence
4	The hydroxl radicals attacked that bond,	4	of carbon-oxygen bond in Mrs. Perry's case?
5	and that's where the pollen becomes oxidized.	5	A I have not done that.
6	And then there is a number of steps in this	6	Q Have you attempted to look for the percent of
7	reaction, I would have to look at a paper to	7	carbon in Mrs. Perry's mesh?
8	explain it, but there is just a number of	8	A I have not done that.
9	steps in that chemical reaction. It's very	9	Q Have you attempted to look for the percent of
10	complex.	10	oxygen in Mrs. Perry's mesh?
11	Q When you say the hydroxl radicals attacked	11	A No.
12	the bond, is that that tertiary bond you were	12	Q You earlier mentioned different biomaterial
13	referring to?	13	books, one of which was your own, I believe?
14	A Yes. It extracts the I would have to look	14	A I edited a book, Introduction to Bond
15	at the paper to show the exact mechanism, but	15	Materials. It's on my CV.
16	that tertiary carbon hydrogen bond is	16	Q What biomaterial books are used at
17	vulnerable to an oxidative attack. But the	17	Vanderbilt?
18	physical chemistry of that reaction is,	18	A So the BME department I mean, chemical
19	again, complex.	19	engineering department, the biomedical
20	Q Is it correct that you have not seen the	20	engineering department, teaches a course in
21	presence of a hydroxl radical in Mrs. Perry's	21	biomaterials. I'm not sure what they're
22	case?	22	using now. In the past, they have used a
23	A Yeah. As we have discussed before, I have	23	book by Johnna Temenoff on biomaterials. I
24	not done the myeloperoxidase staining or	24	think they have made some changes to that
25	looking for a radical, which would be very	25	course. I've never taught that course, so I
	Page 95		Page 97
1	difficult to do in her case. I have not done	1	don't know all the details.
2	that.	2	Q Is your book used in teaching biomaterials
3	Q As I understand it, the presence of hydroxl	3	at Vanderbilt?
4	groups on a surface would be indicative of	4	A Not to my knowledge. But that book was
5	oxidation?	5	written for a somewhat different purpose than
6	A It's the OH group forms in a hydroperoxide	6	for a teaching textbook.
7	intermediate. There is a hydroperoxide that	7	Q I think earlier you mentioned another book
8	forms on the oxidized polypropylene, and we	8	called Biomaterials Sciences, and it had a
9	can see that peak by IR spectroscopy.	9	couple of different editors or authors?
10	Q Have you attempted to do any IR spectroscopy	10	A So there were two well-known books. The
11	in Mrs. Perry's case?	11	older one is well, I think it's called
12	A No, I have not done that.	12	Biomaterials Sciences. It was
13	Q As I understand it, there is testing that can	13	maybe endorsed isn't the word, but the
14	Q As I understand it, there is testing that can be performed to try to assess atomic	14	Society for Biomaterials endorses this book.
14 15	Q As I understand it, there is testing that can be performed to try to assess atomic percents, such as the percent carbon, percent	14 15	Society for Biomaterials endorses this book. Endorses may be a strong word. They
14 15 16	Q As I understand it, there is testing that can be performed to try to assess atomic percents, such as the percent carbon, percent oxygen, and percent nitrogen; is that	14 15 16	Society for Biomaterials endorses this book. Endorses may be a strong word. They recognize this book as being an important
14 15 16 17	Q As I understand it, there is testing that can be performed to try to assess atomic percents, such as the percent carbon, percent oxygen, and percent nitrogen; is that correct?	14 15 16 17	Society for Biomaterials endorses this book. Endorses may be a strong word. They recognize this book as being an important book, and there are four senior authors on
14 15 16 17 18	Q As I understand it, there is testing that can be performed to try to assess atomic percents, such as the percent carbon, percent oxygen, and percent nitrogen; is that correct?A There is a method called x-ray photoelectron	14 15 16 17 18	Society for Biomaterials endorses this book. Endorses may be a strong word. They recognize this book as being an important book, and there are four senior authors on this book.
14 15 16 17 18	 Q As I understand it, there is testing that can be performed to try to assess atomic percents, such as the percent carbon, percent oxygen, and percent nitrogen; is that correct? A There is a method called x-ray photoelectron spectroscopy. We will call it XPS. XPS 	14 15 16 17 18 19	Society for Biomaterials endorses this book. Endorses may be a strong word. They recognize this book as being an important book, and there are four senior authors on this book. It's written more as a reference text.
14 15 16 17 18 19 20	 Q As I understand it, there is testing that can be performed to try to assess atomic percents, such as the percent carbon, percent oxygen, and percent nitrogen; is that correct? A There is a method called x-ray photoelectron spectroscopy. We will call it XPS. XPS tells us what percentage of the carbon is 	14 15 16 17 18 19 20	Society for Biomaterials endorses this book. Endorses may be a strong word. They recognize this book as being an important book, and there are four senior authors on this book. It's written more as a reference text. It's difficult to teach from, because it's an
14 15 16 17 18 19 20 21	 Q As I understand it, there is testing that can be performed to try to assess atomic percents, such as the percent carbon, percent oxygen, and percent nitrogen; is that correct? A There is a method called x-ray photoelectron spectroscopy. We will call it XPS. XPS tells us what percentage of the carbon is bound to other atoms. So in pure 	14 15 16 17 18 19 20 21	Society for Biomaterials endorses this book. Endorses may be a strong word. They recognize this book as being an important book, and there are four senior authors on this book. It's written more as a reference text. It's difficult to teach from, because it's an edited book. So it's an excellent resource
14 15 16 17 18 19 20 21 22	 Q As I understand it, there is testing that can be performed to try to assess atomic percents, such as the percent carbon, percent oxygen, and percent nitrogen; is that correct? A There is a method called x-ray photoelectron spectroscopy. We will call it XPS. XPS tells us what percentage of the carbon is bound to other atoms. So in pure polypropylene, all of the carbons should be 	14 15 16 17 18 19 20 21 22	Society for Biomaterials endorses this book. Endorses may be a strong word. They recognize this book as being an important book, and there are four senior authors on this book. It's written more as a reference text. It's difficult to teach from, because it's an edited book. So it's an excellent resource for study. But for teaching undergraduates,
14 15 16 17 18 19 20 21 22 23	 Q As I understand it, there is testing that can be performed to try to assess atomic percents, such as the percent carbon, percent oxygen, and percent nitrogen; is that correct? A There is a method called x-ray photoelectron spectroscopy. We will call it XPS. XPS tells us what percentage of the carbon is bound to other atoms. So in pure polypropylene, all of the carbons should be bound. Either the hydrogen or carbon, it's a 	14 15 16 17 18 19 20 21 22 23	Society for Biomaterials endorses this book. Endorses may be a strong word. They recognize this book as being an important book, and there are four senior authors on this book. It's written more as a reference text. It's difficult to teach from, because it's an edited book. So it's an excellent resource for study. But for teaching undergraduates, it's not as accessible. So Professor David
14 15 16 17 18 19 20 21 22	 Q As I understand it, there is testing that can be performed to try to assess atomic percents, such as the percent carbon, percent oxygen, and percent nitrogen; is that correct? A There is a method called x-ray photoelectron spectroscopy. We will call it XPS. XPS tells us what percentage of the carbon is bound to other atoms. So in pure polypropylene, all of the carbons should be 	14 15 16 17 18 19 20 21 22	Society for Biomaterials endorses this book. Endorses may be a strong word. They recognize this book as being an important book, and there are four senior authors on this book. It's written more as a reference text. It's difficult to teach from, because it's an edited book. So it's an excellent resource for study. But for teaching undergraduates,

25 (Pages 94 to 97)

	Page 98		Page 100
1	contributed some figures to that textbook.	1	Abbrevo?
2	And Professor Williams' textbook has been	2	A I have not.
3	assessed by my colleagues in BME at	3	Q Have you done any testing of any type on TVT
4	Vanderbilt for teaching. I'm not sure if	4	product for stress incontinence? And when I
5	they've made a final decision whether to use	5	stay TVT, I mean Ethicon's particular TVT
6	it. What's attractive about that book for	6	product.
7	teaching is it's written by one author. So	7	A So only the testing performed at Dr. Dunn's
8	it's a single-author book, and so this is	8	laboratory. Just to be clear, Dr. Dunn did
9	good for teaching undergraduates.	9	that testing. I consulted and advised. We
10	My textbook, I edited, so there are	10	discussed it, agreed to do it, but Dr. Dunn
11	chapters by individual contributors. So it's	11	physically performed the testing.
12	just a different book.	12	Q Tell me what testing did Dr. Dunn do on an
13	Q When you were going about compiling your	13	Ethicon TVT device. As I had read and
14	book, did you reach out to people who you	14	I'll tell you why I'm asking. As I had read
15	felt were experts in certain fields to write	15	your Huskey deposition testimony, he had done
16	or contribute to particular chapters?	16	some testing on maybe one or more AMS meshes
17	A That's how we approached editing the book,	17	and Boston Scientific meshes.
18	that's right. That was in 2005 when I was a	18	A These are new testing that we've done.
19	postdoc.	19	Q Let me just back up then. So as I understand
20	Q What is the most recent edition of your book?	20	it, Dr. Dunn has done some testing on Ethicon
21	Is it on your CV?	21	TVT products?
22	A Well, I co-edited the first edition. There	22	A Yes.
23	is a second edition, but I didn't co-edit	23	Q Are you relying on that testing for your
24	that one. The only one that I have co-edited	24	opinions in the Perry case?
25	has been published in 2006. It's on my CV.	25	A Let me look at my opinions for a minute.
	Page 99		Page 101
1	Q The Society for Biomaterials, you referenced	1	Yes, I am relying on that testing. So I
2	you're a member of that society?	2	should say, I formed my opinions based on the
3	A I am.	3	literature review. My opinions are the same
4	Q And the book they recognize as being an	4	as they were in the Huskey case on this
5	important book is Biomaterials Sciences. Is	5	particular topic of oxidation and
6	the title An Introduction to Materials and	6	degradation, and this testing further
7	Medicine by	7	confirms my opinions.
8	A That sounds right.	8	And the testing was specifically done to
9	Q Buddy Ratner?	9	answer the question that Ethicon raised
10	A Buddy Ratner, Hoffman, Schoen. They're all	10	during the trial in August, that Prolene is
11	founders of the Society for Biomaterials,	11	different from polypropylene and doesn't
12	very well-known. Jack Lemons is the other	12	oxidize because it has antioxidants.
13	author.	13	So in the testing done by Dr. Dunn, the
14	Q Did any of those authors contribute to your	14	goal was to answer the question can Prolene
15	book?	15	in a TVT device oxidize and degrade. And we
16	A I don't remember. I don't think so.	16	saw oxidation and degradation of the surface
17	Q I want to ask you some questions about TVT	17	pitting in that testing, in the oxidative
18	Abbrevo. I'm just trying to give you an idea	18	medium that I was describing earlier. So the
19	of where I'm going.	19	testing was performed to answer a very
20	A Okay.	20	specific question of and to answer the
21	Q Because I know we went back and kind of	21	specific question of can the Prolene
22	covered some things that we addressed earlier	22	polypropylene oxidize. That was the purpose
23	with further questions.	23	of the test.
24	A Okay.	24	Q Where is this testing, all of the notebooks,
25	Q Have you done any testing of any type on TVT	25	the results, the data generated from it that

26 (Pages 98 to 101)

	Page 102		Page 104
1	you are relying on?	1	A I am just disclosing what we did.
2	A So this is on the disk that was provided.	2	Q This TVT retropubic device that Dr. Dunn
3	Q Okay. Show me where on the disk that that is	3	tested, was it one single device or was it a
4	this TVTG testing is located.	4	batch or numerous ones?
5	A I don't have a computer but	5	A I believe it was one device with three
6	Q Can you use Mr. Kuntz'?	6	replicate pieces, three distinct pieces cut
7	MR. KUNTZ: He can.	7	from it was three or four. I can't
8	Let's go off the record for a second.	8	remember the details. I would have to look
9	(Off-the-record discussion.)	9	at it. But there were multiple replicates
10	BY MR. SNELL:	10	cut from the same mesh.
11	Q Counsel is looking at the thumb drive.	11	Q And the unstabilized polypropylene control,
12	Obviously, I can't look at it and question	12	where was that obtained from?
13	the witness about 6,000 files today. Let me	13	A I would have to look at the document to look
14	just get some basic information about this	14	at the documents for the exact source, but it
15	testing.	15	was purchased from a third-party vendor that
16	The testing that was performed on	16	sells polypropylene with antioxidants,
17	Ethicon's TVT mesh, what specific device or	17	unstabilized polypropylene.
18	devices were the subject of the testing?	18	Q Do you know the vendor?
19	A I believe it was the TVT.	19	A I can't remember. It's in the documents. I
20	Q The original TVT retropubic?	20	would have to find it.
21	A I believe so. And we also tested an	21	Q Do you know who purchased this control?
22	unstabilized polypropylene controlled, it had	22	A Dr. Dunn purchased it and did all of this
23	no antioxidant.	23	work.
24	Q Okay. You said it was an unstabilized	24	Q You personally were not the one who did any
25	Prolene polypropylene?	25	of this testing on the TVT retropubic device,
	Page 103		Page 105
1	A No. It's polypropylene without antioxidants.	1	correct?
2	So it would be the equivalent of in the	2	A No. As I said previously, Dr. Dunn and I
3	Liebert paper where they tested the	3	consulted, and Dr. Dunn did all of the work
4	monofilament with no stabilizers. It's a	4	physically through his company.
5	polypropylene that has no antioxidants. So	5	Q So am I correct that you did not do any of
6	it's unstabilized polypropylene I would call	6	the physical testing of this TVT or the
7	it.	7	control?
8	Q So you didn't test the TVT retropubic mesh	8	A That's right. Dr. Dunn did.
9	with antioxidants to the TVT retropubic mesh	9	Q And that was done at his company?
10	with antioxidants?	10	A Yes.
11	A No, we can't get TVT without the the TVT	11	Q Was that testing done out of his house?
12	is made from Prolene that has that Prolene	12	A I don't know. Maybe some of it was done from
13	antioxidant package, because that's what we	13	his house. I don't remember.
14	tested, that's what we could get. So we had	14	Q Do you know where the testing took place on
15	that exemplar, Dr. Dunn had it, and we	15	this TVT retropubic compared to the
16	compared that to the unstabilized	16	polypropylene control?
17	polypropylene. We also tested two Boston	17	A It was done in his lab at Vanderbilt.
18 19	Scientific meshes, but that's not in the	18 19	Q Who paid for the testing that Dr. Dunn
20	materials that we presented. That's different.	20	performed comparing the TVT retropubic to the
21	Q You are not relying on this Boston Scientific	21	unstabilized polypropylene control? A I should clarify that all of these responses
22	testing for your opinions in this matter,	22	I'm telling you to the best of my knowledge.
	correct?	23	And if Dr. Dunn contradicts what I'm saying,
	correct:		
23	Δ I am not	124	it's hecause I didn't remember it correctly
24 25	A I am not. Q Okay.	24 25	it's because I didn't remember it correctly. I believe that this testing was billed to the

27 (Pages 102 to 105)

	Page 106		Page 108
1	litigation, but Dr. Dunn would have to	1	A Same time frame. Maybe August it would
2	confirm that.	2	have been September of 2014 after the Huskey
3	Q Is your basis for your testimony in that	3	trial. And, again, the motivation for the
4	regard something that Dr. Dunn told you?	4	tests was based on Ethicon's statements
5	A Yes, I'm basing it on I have not seen	5	during trial that we had not tested it and
6	those invoices. That would be between	6	couldn't we could not say definitively
7	Dr. Dunn and plaintiff's counsel.	7	that Prolene polypropylene oxidizes, and that
8	Q Did Dr. Dunn physically do all of his	8	was the motivation for the test.
9	testing?	9	So this is what was said in Huskey trial,
10	A Again, I believe that he did, but I don't	10	we decided to do the test to answer that
11	know the details of he would be the one	11	specific question, can Prolene polypropylene
12	that would have to speak to that.	12	oxidize.
13	Q Unfortunately, he is not identified as an	13	Q Now, Dr. Dunn's Vanderbilt lab, is that on
14	expert here.	14	the premises here at Vanderbilt?
15	A I understand that.	15	A Yes, his lab is at Vanderbilt.
16	Q Were you present for any of the physical	16	Q Do you know if any graduate students or
17	testing of the TVT retropubic or the	17	other people were involved in the testing?
18	unstabilized polypropylene control?	18	A Dr. Dunn has employees. I know that. To
19	A Was I present?	19	what extent they were involved in the
20	Q Present meaning on the premises where the	20	testing, I can't speak to. Again, Dr. Dunn
21	testing was performed, such that you could	21	just did all of his. I don't know those
22	yourself observe the testing.	22	details.
23	A Well, the testing was just very simple.	23	I should qualify my comment. Dr. Dunn
24	Dr. Dunn placed the I'm trying to answer	24	does not have employees, but I know that he
25	your question as best I can. So Dr. Dunn	25	does pay contractors for services like he
	Page 107		Page 109
1	placed the specimens in vials. They were	1	pays me. But, again, I cannot speak to how
2	weighted down with glass beads in this	2	he conducts his business.
3	oxidative medium that I was describing that	3	Q Why did Dr. Dunn choose to test only one TVT
4	simulates the environment between the	4	retropubic device?
5	adherent inflammatory cells and the	5	A That was what we had at the time. And we
6	biomaterial. I have seen those vials.	6	knew these depositions and report deadlines
7	And then at different time points,	7	were approaching quickly, so we moved forward
8	Dr. Dunn removed the test specimens, rinsed	8	with what we had.
9	and dried them, and measured RI spectra. And	9	Q Would you have preferred to have more than
10	I've seen those dried specimens. I've seen	10	one TVT retropubic to test?
11	the specimens, and so I have seen aspects of	11	A We requested additional exemplars from
12	the testing, but I didn't watch him do the	12	plaintiff's counsel. My understanding is
13	testing. But the testing essentially	13	that this is a complex request and takes
14		1 1 1	time. We have requested additional items
	involves incubating the material in a	14	time. We have requested additional items
15	solution, and then taking it out and testing	15	recognizing the need to test multiple
16	solution, and then taking it out and testing it by FTIR and SEM.	15 16	recognizing the need to test multiple meshes. But as I said, these requests can
16 17	solution, and then taking it out and testing it by FTIR and SEM. Q When was this testing on the TVT retropubic	15 16 17	recognizing the need to test multiple meshes. But as I said, these requests can take time to process, so we tested what we
16 17 18	solution, and then taking it out and testing it by FTIR and SEM. Q When was this testing on the TVT retropubic device done?	15 16 17 18	recognizing the need to test multiple meshes. But as I said, these requests can take time to process, so we tested what we had.
16 17 18 19	solution, and then taking it out and testing it by FTIR and SEM. Q When was this testing on the TVT retropubic device done? A September and October of 2014.	15 16 17 18 19	recognizing the need to test multiple meshes. But as I said, these requests can take time to process, so we tested what we had. Q Why is there a need to test multiple meshes?
16 17 18 19 20	solution, and then taking it out and testing it by FTIR and SEM. Q When was this testing on the TVT retropubic device done? A September and October of 2014. Q And it was on a single TVT retropubic	15 16 17 18 19 20	recognizing the need to test multiple meshes. But as I said, these requests can take time to process, so we tested what we had. Q Why is there a need to test multiple meshes? A I should qualify my answer I need to test.
16 17 18 19 20 21	solution, and then taking it out and testing it by FTIR and SEM. Q When was this testing on the TVT retropubic device done? A September and October of 2014. Q And it was on a single TVT retropubic exemplar, meaning that mesh had not been in	15 16 17 18 19 20 21	recognizing the need to test multiple meshes. But as I said, these requests can take time to process, so we tested what we had. Q Why is there a need to test multiple meshes? A I should qualify my answer I need to test. By testing multiple products, it's possible
16 17 18 19 20 21 22	solution, and then taking it out and testing it by FTIR and SEM. Q When was this testing on the TVT retropubic device done? A September and October of 2014. Q And it was on a single TVT retropubic exemplar, meaning that mesh had not been in the body at all?	15 16 17 18 19 20 21 22	recognizing the need to test multiple meshes. But as I said, these requests can take time to process, so we tested what we had. Q Why is there a need to test multiple meshes? A I should qualify my answer I need to test. By testing multiple products, it's possible to show that it would happen in many of these
16 17 18 19 20 21 22 23	solution, and then taking it out and testing it by FTIR and SEM. Q When was this testing on the TVT retropubic device done? A September and October of 2014. Q And it was on a single TVT retropubic exemplar, meaning that mesh had not been in the body at all? A That's correct.	15 16 17 18 19 20 21 22 23	recognizing the need to test multiple meshes. But as I said, these requests can take time to process, so we tested what we had. Q Why is there a need to test multiple meshes? A I should qualify my answer I need to test. By testing multiple products, it's possible to show that it would happen in many of these products. It's not possible to test every
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28 (Pages 106 to 109)

	Page 110		Page 112
1	intrinsic molecular structure of	1	Journal of Biomedical Materials Research. In
2	polypropylene, as well as the antioxidant	2	the 1990 paper is a seminal paper where
3	package, if those things are all the same,	3	Dr. Anderson discovered the effects of the
4	you would expect a very similar response.	4	foreign body reaction on a biomedical device.
5	Like I said, it's a chemical reaction.	5	The 1993 paper he simulated. He
6	So if it's the same material with the same	6	reproduced or recapitulated that same
7	antioxidants, you would expect to see a very	7	oxidation and degradation in that same
8	similar chemical reaction. We tested two	8	biomaterial in vitro outside the body. So he
9	Boston Scientific meshes because we had to.	9	was able to show that this solution, this
10	If we had had more, we could have tested more	10	oxidative solution that I've been talking
11	and would have liked to have done that, but	11	about recapitulates the oxidative conditions
12	we were limited to what we had at the time.	12	that the biomaterial was exposed to in vitro.
13	MR. SNELL: I'm going to move to	13	I should qualify my previous comment when
14	strike the part about Boston Scientific.	14	I said there is no cells. There is no other
15	A I understand. I shouldn't have said that.	15	cell populations like fibroblasts that are
16	I'm sorry.	16	exerting contractile forces. There is no
17	BY MR. SNELL:	17	tissue that is exerting forces. So this test
18		18	
19	Q So you would expect to see a similar response	19	is isolating the effects of chemical
20	you said, correct? A Yes.	20	oxidation and was found to agree with in vivo
21		21	observations. That's the purpose of the
22	Q If you tested multiple meshes, correct?A I would.	22	test, and those two papers have shown that.
23		23	So I hope I'm answering your question.
24	Q But we know from the teachings of Clave that	24	It reproduces certain aspects of the
25	not all findings will be consistent with	25	reaction, but not every but the ones that
25	regard to degradation, correct?	25	I just mentioned.
	Page 111		Page 113
1	MR. KUNTZ: Objection.	1	Q The test that was done on the TVT device does
2	A I think that the conditions are very	2	not establish that an oxidative condition
3	different. Clave is in vivo explant, so	3	occurs in vivo; is that correct?
4	there are many different factors affecting	4	MR. KUNTZ: Objection.
5	oxidation. This study was purely isolating	5	A Let me the in vitro test does not
6	the chemical reaction. The medium that we	6	establish the in vivo conditions. It's
7	used has been published by a number of	7	recapitulating those in vivo conditions. We
8	investigators, including me, that simulates	8	know that this happens in the foreign body
9	the oxidative conditions in the body.	9	reaction, and so the test is designed to
10	So we're simulating a chemical reaction,	10	recapitulate that foreign body reaction in
11	not there is no cells. There is no	11	the laboratory.
12	tissue. It is simply examining that chemical	12	Q What are the limitations to the test as it
13		13	was conducted by Dr. Dunn utilizing only one
	reaction, will that chemical reaction cause a		
14	change in Prolene polypropylene. That was	14	TVT device?
14 15	change in Prolene polypropylene. That was the purpose of the test, so it's very	14 15	TVT device? A Well, the limitation of the test is I want
14 15 16	change in Prolene polypropylene. That was the purpose of the test, so it's very different from, say, Clave's study. It is	14 15 16	TVT device? A Well, the limitation of the test is I want to be very careful about my opinion. The
14 15 16 17	change in Prolene polypropylene. That was the purpose of the test, so it's very different from, say, Clave's study. It is very specific.	14 15 16 17	TVT device? A Well, the limitation of the test is I want to be very careful about my opinion. The question we were asking was and what I was
14 15 16 17 18	change in Prolene polypropylene. That was the purpose of the test, so it's very different from, say, Clave's study. It is very specific. That is why I would expect to see the	14 15 16 17 18	TVT device? A Well, the limitation of the test is I want to be very careful about my opinion. The question we were asking was and what I was presented with in trial, and I believe what
14 15 16 17 18 19	change in Prolene polypropylene. That was the purpose of the test, so it's very different from, say, Clave's study. It is very specific. That is why I would expect to see the same changes in any mesh that we tested.	14 15 16 17 18 19	TVT device? A Well, the limitation of the test is I want to be very careful about my opinion. The question we were asking was and what I was presented with in trial, and I believe what Dr. Shelby Thames testified for defense was
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29 (Pages 110 to 113)

	Page 114		Page 116
1	polypropylene oxidized. We have also showed	1	events.
2	evidence of pitting and surface degradation.	2	It starts to oxidize immediately when
3		3	it's implanted. It's colonized by
4	So the limitation would be, we're not saying	4	<u>.</u>
	that we saw it in every mesh, we're not		macrophages. I believe with a reasonable
5	saying we saw it in 10,000 meshes. We're	5	degree of scientific certainty it will start
6	saying we saw it in one mesh. And we	6	to oxidize upon implantation. When it
7	answered this question that it can oxidize.	7	becomes induced, and there are much more
8	Because it's a chemical reaction, I believe	8	dramatic changes in physical properties is
9	we would see it in other meshes if we tested	9	unpredictable, as I've said in previous
10	those, but I recognize that we didn't. We	10	testimony. Those events are unpredictable.
11	tested one mesh, but we did show that it can	11	But I do believe that the test tells us
12	happen in that one mesh.	12	that the mesh can oxidize, and I would expect
13	Q So with that said, let's go back to my	13	it to oxidize under in vivo conditions due to
14	question. What are the limitations of the	14	the nature of the inflammatory response that
15	testing that Dr. Dunn did given there was	15	we discussed.
16	only one TVT mesh?	16	MR. SNELL: Move to strike.
17	MR. KUNTZ: Objection, asked and	17	BY MR. SNELL:
18	answered.	18	Q One of the limitations to the test that
19	A I thought I answered it. I will try a	19	Dr. Dunn did on the single TVT retropubic
20	briefer answer. The limitation would be that	20	device was that it does not establish that
21	we tested one mesh. We showed that it can	21	Prolene polypropylene degrades in vivo; is
22	happen. We did not estimate a probability	22	that correct?
23	that it would happen. We tested one mesh and	23	A It does not establish? I'm having a hard
24	saw that it happened in that mesh that we	24	time with this word establish. It supports
25	tested.	25	my opinions that these meshes are can
	Page 115		Page 117
1	I believe the literature teaches with a	1	oxidize and degrade in vivo.
2	reasonable degree of scientific certainty	2	Q I'm not asking you whether your
3	that it would happen in other meshes because	3	interpretation as to whether it supports your
4	presumably they are chemically the same. I	4	opinion.
5	didn't look at necessarily the manufacturing	5	MR. SNELL: So I would
6	doc, but I would presume based on my industry	6	respectfully move to strike.
7	experience that there are specifications for	7	BY MR. SNELL:
8	antioxidants and Prolene. I've seen some	8	Q The limitation to this test that Dr. Dunn did
9	documents showings those numbers. Provided	9	on the single TVT is that it does not
10	those compositions are the same, I would	10	establish that Prolene polypropylene degrades
11	expect to see a very similar result, because	11	in vivo; is that correct?
12	it is a chemical test testing the effects of	12	MR. KUNTZ: Objection. He said
13	a specific chemical reaction.	13	the exact same opposite.
14	BY MR. SNELL:	14	A I'm struggling with the way you phrased the
15	Q Is it fair to say that one of the limitations	15	question. I don't want to agree to that. I
16	with that test is that it does not establish	16	believe with a reasonable degree of
17	that Prolene polypropylene degrades in vivo?	17	scientific certainty that this test predicts
18	MR. KUNTZ: Objection.	18	susceptibility to oxidative degradation. And
19	A I would say it doesn't establish the timing	19	if we see it in vitro, we will see it in
20	in which Prolene polypropylene oxidizes in	20	vivo.
21	vivo. The time scale at which this happens	21	It's just the timing and the severity are
22	would depend on many other factors, the	22	unpredictable, but I do believe it will
23	environment, the patient, I understand that,	23	happen. I think that it's the timing and
24	but I do believe that it shows that it would	24	the severity, the clinical consequences are
25	oxidize. It's just the timing of those	25	unpredictable. That's what I've been saying.

30 (Pages 114 to 117)

	Page 118		Page 120
1	MR. SNELL: Well, I respectfully	1	performed; is that correct?
2	move to strike again.	2	A You're misunderstanding the purpose of the
3	BY MR. SNELL:	3	test.
4	Q Again, I'm not asking you about	4	Q Sir, you have to listen to my questions and
5	susceptibility to oxidation, and I'm not	5	answer them yes or no or whatever. I'm not
6	asking you about oxidation, that particular	6	asking you about the purpose of the test and
7	step. I'm asking you about degradation in	7	all of that.
8	vivo.	8	A That cannot be answered by a yes or no
9	So the question again. One of the	9	question. The macrophage is not there, but
10	limitations to those tests by Dr. Dunn on the	10	the consequence of the macrophage is there.
11	single TVT is that it does not establish that	11	That's the test.
12	Prolene polypropylene degrades in vivo; is	12	MR. SNELL: Move to strike.
13	that a fair statement?	13	BY MR. SNELL:
14	MR. KUNTZ: Objection.	14	Q What macrophage
15	A You're speaking specifically of degradation?	15	A I'm not going down on this. Go ahead. I'm
16	BY MR. SNELL:	16	sorry.
17	Q Yes, sir. That's why my question only said	17	Q Were macrophages present in the test that
18	degradation.	18	Dr. Dunn did on the single TVT retropubic?
19	A Okay. I would like to explain my answer on	19	A Macrophages were not present, but what
20	this.	20	macrophages produce, meaning radicals and
21	Q Can you first agree or disagree and then	21	reactive oxygen was present. We generated
22	please feel free to explain?	22	those reactive species using a chemical
23	A So you're saying that it does not establish	23	reaction instead of a macrophage, but this is
24	that it degrades	24	an acceptable accepted approach to doing
25	Q I will ask it one more time.	25	that.
	Page 119		Page 121
1	A I'm trying to give you an accurate answer,	1	Just because a macrophage was not there
2	A I'm trying to give you an accurate answer, and I'm struggling with how to answer this.	2	Just because a macrophage was not there doesn't mean it's the same oxidative
2	A I'm trying to give you an accurate answer, and I'm struggling with how to answer this.Q One of the limitations to the test that	2	Just because a macrophage was not there doesn't mean it's the same oxidative conditions. It's just accomplished through a
2 3 4	A I'm trying to give you an accurate answer, and I'm struggling with how to answer this.Q One of the limitations to the test that Dr. Dunn performed on this single TVT	2 3 4	Just because a macrophage was not there doesn't mean it's the same oxidative conditions. It's just accomplished through a different chemical reaction.
2 3 4 5	 A I'm trying to give you an accurate answer, and I'm struggling with how to answer this. Q One of the limitations to the test that Dr. Dunn performed on this single TVT retropubic device was that it does not 	2 3 4 5	Just because a macrophage was not there doesn't mean it's the same oxidative conditions. It's just accomplished through a different chemical reaction. MR. SNELL: Move to strike
2 3 4 5 6	 A I'm trying to give you an accurate answer, and I'm struggling with how to answer this. Q One of the limitations to the test that Dr. Dunn performed on this single TVT retropubic device was that it does not establish that Prolene polypropylene degrades 	2 3 4 5 6	Just because a macrophage was not there doesn't mean it's the same oxidative conditions. It's just accomplished through a different chemical reaction. MR. SNELL: Move to strike everything after macrophage was not present.
2 3 4 5 6 7	A I'm trying to give you an accurate answer, and I'm struggling with how to answer this. Q One of the limitations to the test that Dr. Dunn performed on this single TVT retropubic device was that it does not establish that Prolene polypropylene degrades in vivo; is that a fair statement?	2 3 4 5 6 7	Just because a macrophage was not there doesn't mean it's the same oxidative conditions. It's just accomplished through a different chemical reaction. MR. SNELL: Move to strike everything after macrophage was not present. A I'm not going to back down. We can stay here
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31 (Pages 118 to 121)

	Page 122		Page 124
1	obligation under California state law to do	1	is it that you believe this test on this
2	that. We have complied. We have brought a	2	single TVT device compared to the control
3	disk and brought the materials responsive to	3	shows?
4	the deposition. That is the only thing that	4	A I believe that it shows Prolene polypropylene
5	is required under California law. I want to	5	used to manufacture the TVT device can
6	make this clear. We have no duty to produce	6	oxidize and degrade under oxidative
7	before the depo anything, zero.	7	conditions similar to those experienced in
8	MR. SNELL: That's fine, if	8	the human body after implantation.
9	that's your position.	9	Q What documents or files out of those 6,000
10	MR. KUNTZ: Okay.	10	plus show the oxidation?
11	BY MR. SNELL:	11	A The oxidation is evidenced by FTIRs spectra
12	Q Am I correct, sir, that there were no foreign	12	that were measured in weeks zero, one, two,
13	body giant cells that were used in Dr. Dunn's	13	three, four and five. In the FTIRs spectra,
14	test?	14	we saw minimal hydroxl and carbonyl peaks
15	A My answer is the same. The cells weren't	15	until week five, where we saw a significant
16	there, but the reaction products were.	16	increase in the magnitude of the hydroxl
17	MR. SNELL: Move to strike after	17	and/or carbonyl peaks, which was indicative
18	the cells were not there.	18	of a chemical induction.
19	A These are unreasonable questions. And this	19	Q So what are the file names and the documents
20	deposition is going to get more hostile if	20	that showed this out of the 6,000?
21	you keep going down this line of questioning,	21	A I don't remember the file names.
22	just to put it out there.	22	Q Well, I'm entitled to know them.
23	Q Sir, as the witness, I'm allowed to ask you	23	A I know. And I have to look at it. I don't
24	questions. You may not like the question,	24	have it here with me. I know that you're
25	but you have to answer the questions.	25	entitled to have it, but I don't have it here
	Page 123		Page 125
1	A But the questions are being phrased that	1	in front of me.
2	you're trying to misrepresent my testimony	2	MR. KUNTZ: He does have it.
3	and misrepresent what I'm saying.	3	MR. SNELL: Out of the 6,000,
4	Q I'm not trying to misrepresent your	4	you think I am some kind of scientist and can
5	testimony.	5	pick out this FTIR testing?
6	A You are.	6	MR. KUNTZ: The rules are the
7	Q I'm asking you a factual question.	7	rules, Burt. You gave us testing two weeks
8	A And the question is	8	before trial. I don't cry about it. We
9	Q Was there a horse in the room at the time of	9	follow the rules.
10	the test, yes or no? No.	10	MR. SNELL: All I'm asking him
11	Was there a macrophage in the test, yes	11	is to identify it.
12	or no?	12	MR. KUNTZ: That's fine. We'll
13	The interpretation, I will get to that,	13	sit here and he can identify it. Let's pull
14	but I have simple questions, sir, and I'm	14	it up.
15	entitled to simple answers if they're simple	15	MR. SNELL: That's what I
16	questions. You can talk to Mr. Kuntz all	16	thought we were doing.
17	night long about your interpretation. That's	17	MR. KUNTZ: If that's how you
18	fine. But I'm actually going to ask you	18	want to spend your seven hours with him,
19	about your interpretation too.	19	let's do it.
20	A And I'm entitled to answer questions as I	20	MR: BOWMAN: There is a folder
21	need to. And I'm not going to be put into	21	named FTIR on the drive that was given to
22	this difficult position of having things	22	you. It's already been disassembled and
23	recorded as my testimony that's not what I've	23	separated out. There's FTIR, and there's
			CEM 1 VDC
24 25	ever been saying. Q You would agree that let me back up. What	24 25	SEM, and XPS. MR. KUNTZ: I'm trying to get

32 (Pages 122 to 125)

1 you a link, so you can pull them up. 2 BY MR. SNELL. 3 Q What documents, if any, in this study that 4 Dr. Dunn did on the single TVT device show 4 that the Prolene polypropylene degrades? 5 A There are SEM images at weeks zero and five, 1 believe. What the name of that file is, I 2 don't know. I will have to look at the 5 folders to try to find it. 2 which wood days are the standard of the sta		Page 126		Page 128
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The lieve. What the name of that file is, I So XPS, we did three distinct measurements at three surfaces on the fiber. We cannot see microscopically where we're testing, so it's not possible to tell whether we're testing where there is an area of active degradation or not. Does that make sense?		that the Prolene polypropylene degrades?	5	carbon-oxygen bonds on the surface of the
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folders to try to find it. Q Okay. And what is it about those SEM images that you believe shows degradation? A There are changes in the surface, including pitting, flaking, changes to the surface that can be observed by SEM. A I don't know. I would have to look at the image again to see it. Q How much material is flaking off? A Again, I would have to look at it to see that. We saw SEM is we were just really looking to see if it's there or not. It's difficult to be more quantitative as we can be observed by sift be pitting? A We were working on it. In the amount of time we had to pull this together, we haven't had time to do it yet. Q Not yet? A Not, degradation A There surfaces on the fiber. We cannot see microscopically where we're testing, on to possible to tell whether we're testing where there is an area of active degradation or or not. Does that make sense? There is areas of pitting on the fibers, and then there is areas on the fibers where don's not possible to tell whether we're testing where there is an area of active degradation or or not. Does that make sense? There is areas of pitting on the fibers, and then there is areas on the fibers where don's not possible to tell whether we're testing where there is an area of active degradation or or not. Does that make sense? There is areas on the fibers where we're testing on the intervient sense. There is areas of pitting on the fibers, and then there is areas on the fibers where don's not possible to tell whether we're rotes. There is areas of pitting on the fibers, and then there is areas on the fibers where on the fiber we're probing. There is areas on the fibers where we're toes use of pitting. There is areas on the fibers where we're testing where there is an area of active degradation or not. It's tell us at that particular spot that is being probed, what the percentage of the carbon is bound to oxygen. And we saw many spois on the surface. Q Did you attempted to quantify the amount	7	I believe. What the name of that file is, I	7	Q How many carbon-oxygen bonds were seen?
10 Q Okay. And what is it about those SEM images that you believe shows degradation? 11 A There are changes in the surface, including pitting, flaking, changes to the surface that can be observed by SEM. 12 Q How deep is the pitting? 13 In a Hon's large again to see it. 14 Can be observed by SEM. 15 Q How deep is the pitting? 16 A I don't know. I would have to look at the image again to see it. 17 In age again to see it. 18 Q How much material is flaking off? 18 Q How much material is flaking off? 19 A Again, I would have to look at it to see that. We saw SEM is we were just really looking to see if it's there or not. It's looking to see if it's there or not. It's difficult to be more quantitative as we can be with the FTIR, but we saw evidence of changes to the surface. 20 Did you attempt to quantify the pitting? 21 A We were working on it. In the amount of time we had to pull this together, we haven't had the rod oit yet. 22 There is a area of pitting on the fibers, and then there is areas on the fibers that we don't see the pitting. When we do the XPS measurement, we're not exactly sure of where on the fiber we're probing. We actually picked three spots. And the XPS measurement tells us at that particular spot that is being probed, what the percentage of the carbon is bound to oxygen. And we saw many spots. It's in the data. I just can't remember the exact numbers, but we saw many spots on the surface there is one of the samples. What here or on the surface there is a raea on the fibers that we don't see the pitting. When we do the XPS measurement tells us at that particular spot that is being probed, what the percentage of the carbon is bound to oxygen. And we saw many spots. It's in the data. I just can't remember, we're not exactly sure of where on the fiber we're probing. We actually problemed that is being probed, what the percentage of the carbon is bound to oxygen bonds? A We were working on it. In the amount of time we had to pull this together, we haven't had the treatment of the surface. 22	8	don't know. I will have to look at the	8	A So XPS, we did three distinct measurements at
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18 Q How much material is flaking off? A Again, I would have to look at it to see 19 that. We saw SEM is we were just really 20 to latt. We saw SEM is we were just really 21 looking to see if it's there or not. It's 22 difficult to be more quantitative as we can 23 be with the FTIR, but we saw evidence of 24 changes to the surface. 25 Q Did you attempt to quantify the pitting? 26 A We were working on it. In the amount of time 27 we had to pull this together, we haven't had 28 time to do it yet. 29 Q You attempted to quantify the amount of 20 flaking? 3 A Same answer. 4 Q You attempted to quantify the amount of 5 flaking? 5 A Not yet. 9 Q Is there anything else about this test that 10 Dr. Dunn did on the single TVT device? 11 A Anything else that I'm sorry. Go ahead. 12 Q That's okay. 13 A It shows degradation besides the SEM images? 14 A No, degradation was assessed by FTIR? 15 A No, degradation was assessed by FTIR? 16 Q Oxidation was assessed by FTIR? 17 A That's correct. And there was XPS testing for some of those samples as well. 19 Q You said there was XPS testing for some of the samples. What do you mean? 20 the fiber we're probing. We actually picked three spots. And the XPS measurement talis being probed, what the percentage of the carbon is bound to oxygen. And we saw many spots. It's in the data. I just can't remember the exact numbers, but we saw many spots on the surface where we saw the Page 129 existence of carbon-oxygen bonds. 2 Q Should there be no carbon-oxygen bonds? A There should be no carbon-oxygen bonds? A There should be no carbon-oxygen bonds in nonoxidized polypropylene, polypropylene that has not been oxidized. I don't want to use polypropylene that has not been oxidized. 5 Should there be no carbon-oxygen bonds. 6 Should there be no carbon-oxygen bonds. 7 Q Not yet? 8 A Not yet. 9 Q Is there anything else about this test that 10 D. Dunn did on the single TVT device? 11 A Netll in the AVB mand to purple a carbon in the data. I just can't remember all of the time po		A I don't know. I would have to look at the	16	don't see the pitting. When we do the XPS
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33 (Pages 126 to 129)

	Page 130		Page 132
1	pellet was from? Is that in the files?	1	each time point because we have three or four
2	A I believe that it is. If it's not, we can	2	replicates.
3	get that. That's a known. Dr. Dunn has that	3	I can't remember the exact number, but we
4	information. And I should note that Dr. Dunn	4	have enough replicates that we can speak to
5	has all of the samples from this testing as	5	the significant differences between groups
6	well. We still have the material. We saved	6	as a function of time.
7	everything.	7	Q But that analysis has not been done yet,
8	Q Is it kept at his lab or his house?	8	correct?
9	A I'm not sure where he is storing that, but he	9	A It has not been done because we are still
10	has stored that in dark containers protected	10	quantifying the results.
11	from the light. He can speak to that. He's	11	Q Who will do the testing for clinical
12	storing the material. I'm not sure where.	12	significance?
13	Q So this polypropylene pellet that was used as	13	A I don't know yet. We're still discussing
14	an unstabilized control, am I correct that it	14	this.
15	had not been extruded or gone through any	15	Q Who are you considering to do statistical
16	manufacturing process whatsoever?	16	significance testing in this test
17	A I believe that it had probably at least been	17	A Dr. Dunn or I. One of us will do it.
18	extruded because we bought it as pellets. So	18	Q Are you a statistician?
19	my understanding is they melt the	19	A I'm not a statistician, but I've done similar
20	polypropylene I don't know the answer to	20	statistical testing in any papers that I've
21	that. Dr. Dunn would be able to talk about	21	published where we compared differences
22	the history of the sample.	22	between material groups and time using a one-
23	Q Do you know if this polypropylene pellet that	23	or two-way ANOVA. That's a common method.
24	you tested was a pellet used in any stress	24	Q But you're going to be testing over different
25	incontinence sling devices?	25	time points, correct?
	Page 131		Page 133
1	A I have no way of knowing that without knowing	1	A You mean statistically?
2	the supplier of the pellet.	2	Q Yeah.
3	Q How was it that Dr. Dunn came to decide on	3	So you will be testing over multiple time
4	which particular polypropylene pellet from a	4	points, correct?
5	certain manufacturer he was going to obtain?	5	A Yes.
6	A So in his previous testimony, Dr. Dunn has	6	Q So, therefore, you will need to apply a
7	investigated a number of polypropylene cases,	7	Bonferroni or some type of multiple testing
8	and he's done similar testing before in which	8	equation, correct?
9	he used unstabilized polypropylene controls,	9	A Yes. We typically do this. I believe it
10	so that decision would have been based on his	10	will be a two-way ANOVA with a Bonferroni
11	experience with prior testing.	11	correction. But, again, we haven't decided
12	Q The unstabilized polypropylene control, what	12	that yet.
13	tests were done that on that?	13	Q So as you sit here today, you cannot state
14	A The same tests as were done on TVT. So it	14	that the test results were statistically
15	would have been XPS, FTIR and SEM.	15	significant upon applying the proper
16	Q Did you attempt to calculate any clinical	16	statistical testing?
17	significance of any findings in this test	17	A We haven't done it yet. The differences
18	that Dr. Dunn did?	18	appear to be large, but we have to do the
19	A We are still doing the quantitative analysis,	19	statistics for the FTIR testing. I don't
20	but we will calculate how shall I say this	20	know what we will be able to do yet on the
21	statistical significance between groups as	21	SEM. We are discussing that.
22	a function of time. So we would compare the	22	Q So the FTIR testing is the testing that you
23	TVT group to the unstabilized polypropylene	23	intend to do statistical significance testing
24 25	group. We would compare at each time point.	24	upon?
L 40	And we would compare within each group at	25	A Yes.

34 (Pages 130 to 133)

1 Q And the SEM images, because you only took them at limited time points, zero and five when at limited time points, zero and five second that to generate statistical significant findings? 5 MR. KUNTZ: Objection. 6 MR. KUNTZ: Objection. 8 SEM, we are looking at specific locations. 9 We can't sample the entire mesh area. So it's - we're evaluating. We haven't decided yet what to do with it. 12 BY MR. SNELL: 13 Q Is it fair to say as you sit here today, you that have not decided whether or not to do statistically significant calculations upon the EME by the surface of the mesh, so we have a similar sampling concern. So we haven't yet ecided - with XPS we were more interested in 14 A That's right. 15 A Not yet. XPS is similar to SEM, in that we're limited to a relatively small area on the surface of the mesh, so we have a similar sampling concern. So we haven't yet decided - with XPS we were more interested in 15 Page 135 1 confirming the existence of those carbon-oxygen bonds. 16 XPS is a useful technique for showing that the carbon is, in fact, chemically bound to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we medicular weight in this test? 1 A Well, you had a whole sling, on, correct? 2 A Molt we will have teaching before a calculations and the stractive at the FTIR and the SEM would provide similar informative. So then the material erequirements for doing that testing are pretry limiting, so we didn't do it. 2 A That's right. 2 A Not yet. XPS is similar to SEM, in that we're limiting, so we have a similar sampling concern. So we have		Page 134		Page 136
them at limited time points, zero and five enough data to generate statistical senough data to generate statistical significant findings? MR. KUNTZ: Objection. A I wouldn't say it that way. I would say in SSEM, we are looking at specific locations. We can't sample the entire mesh area. So it is "- we're evaluating. We haven't decided yet what to do with it. BYMR. SNELL: BYMR. SNELL: BYMR. SNELL: O For the XPS portion of this test, have you attended to the SEM testing part of the test? A Not yet. XPS is similar to SEM, in that eachlations? A Not yet. XPS is similar to SEM, in that we're limited to a relatively small area on the surface of the mesh, so we have a similar sampling concern. So we haven't yet decided — with XPS we were more interested in to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen honds. XPS is a useful technique for showing that the carbon is, in fact, chemically bound to the coxygen. And so we use XPS as a method to the oxygen. And so we use XPS as a method to the oxygen honds. Q But to date, no statistical significance testing has been done on the XPS portion; is that right? A Has not been done. Q Did you attempt to analyze molecular weight in molecular weight measurements require a considerable amount of material. Molecular weight measurements also aren't as — with molecular weight measurements require a considerable amount of material. Molecular weight measurements also aren't as — with molecular weight measurements require a considerable amount of material. Molecular weight measurements also aren't as — with molecular weight measurements also aren't as — with molecular w	1	O And the SEM images because you only took	1	O Well you had a whole sling correct?
weeks, you do not know whether there is enough data to generate statistical significant findings? MR. KUNTZ: Objection. A I wouldn't say it that way. I would say in SEM, we are looking at specific locations. We can't sample the entire mesh area. So it's - we're evaluating. We haven't decided yethat to do with it. BY MR. SNELL: Q Is it fair to say as you sit here today, you haven't decided whether or not to do statistically significant calculations upon the SEM testing part of the test? A That's right. Q For the XPS portion of this test, have you attempted to do any statistical significance calculations? 10 attempted to do any statistical significance calculations? 11 confirming the existence of those carbon-oxygen bonds. XPS is a useful technique for showing that the carbon is, in fact, chemically bound to to boxygen. And so we use XPS as a method to support the FTIR findings. Q But to date, no statistically significance testing has been done on the XPS portion; is that right? A We did not. Q Did you attempt to analyze molecular weight measurements require a considerable amount of material. Molecular weight measurements also aren't as - with molecular weight, these other methods, it's more the surface of the most informative. So then the material continements for doing that testing are pretty limiting, so we didn't do it. We believed that the FTIR and the SEM would provide similar informative. So then the material requirements for doing that testing are pretty limiting, so we didn't do it. We believed that the FTIR and the SEM would provide similar informative. So then the material nequirements for doing that testing are pretty limiting, so we didn't do it. We believed that the FTIR and the SEM would we be bettered that the FTIR and the surface. And FTIR and SEM are commonly used by many investigators in these types of studies. So that's why				- •
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45 we are doing this reaction in vitro by [45 changes it s valenced.	25	we are doing this reaction in vitro by	25	changes it's valenced.

36 (Pages 138 to 141)

	Page 142		Page 144
1	But the main reaction product is that	1	implanted subcutaneously. That was the
2	hydroxl radical that's simulating the	2	purpose of that control was to give us some
3	reactive oxygen species formed by these	3	idea of the relative time scale to relate our
4	inflammatory cells in vivo.	4	tests to in vivo conditions as an
5	Q Okay. So the hydroxl radical simulates the	5	approximation.
6	reactive oxygen species from the macrophages	6	Q In vivo in a hamster, though, not a person?
7	in foreign body giant cells?	7	A Yes, in vivo in a hamster in a subcutaneous
8	A It is. So the foreign body giant cells and	8	space, not the pelvic it could be much
9	macrophages produce a number of reactive	9	faster in a pelvic floor. But it was a
10	oxygen species, and hydroxl radicals are one	10	suture implanted subcutaneously is what
11	of them. So in the in vitro test, we are	11	Liebert did.
12	producing those hydroxl radicals and the	12	Q What is the rate of induction of Prolene
13	Bonferroni ROS species produced by the	13	polypropylene in the pelvic floor?
14	inflammatory cells in vivo or in vitro. They	14	A We cannot determine that from this test.
15	do this in vitro as well.	15	There are many factors that affect that.
16	Q How do you know that macrophages in foreign	16	Q Is it correct that you do not know how much
17	giant body cells produce hydroxl radicals in	17	of the hydroxl radical is produced in the
18	any particular case?	18	solution used by Dr. Dunn?
19	A It's been published in the Dr. Anderson	19	A I'm not sure if that's known how no, I
20	papers that I mentioned that when these	20	don't know that we know that, but
21	inflammatory cells adhere to the biomaterial	21	Q Well, let's see if we can do this. It would
22	surface, they secrete a number of these	22	seem to me to be common sense that the amount
23	reactive oxygen species, including the	23	of hydroxl radicals that would be produced in
24	hydroxl radicals.	24	vivo would be somewhat dependent upon the
25	Q How much hydroxl radical do they produce?	25	number of macrophages; is that correct?
	Page 143		Page 145
1	A I don't know that anybody has measured that.	1	A That would be one factor. The extent of the
2	Q How much hydroxl radical is produced in this	2	inflammatory reaction would be one factor
3	test that mesh was put into?	3	that would affect induction time.
4	A We don't know. But the reason we ran the	4	Q So if there were 1,000 macrophages present,
5	polypropylene control, I can try to answer	5	the ability of hydroxl radicals to be
6	that. So we know from Liebert, Liebert took	6	produced quantity-wise would be much greater
7	the monofilament, the unstabilized	7	than if only ten macrophages were present.
8	polypropylene, and planted it subcutaneously	8	Is that a fair scientific statement?
9	in a hamster, and he saw a chemical	9	A You're saying that you would expect more ROS
10	induction. He saw oxidation induction of	10	with more macrophages? Is that what you're
11	this oxidation reaction at 108 days. Okay.	11	saying?
12	So in our study that is 108 days to	12	Q No.
13	induction. That is in vivo in that hamster	13	A Okay. Say it again. I didn't get it.
14	model, in vivo in the hamster model. In our	14	Q The potential amount of hydroxl radicals that
15	study, we saw induction between days 21 and	15	could be produced would be higher if there
16	28 for unstabilized polypropylene control.	16	were 1,000 macrophages present as opposed to
17	So if you average that, just to give you an	17	only ten. Is that a fair scientific
18	approximation to try to answer your question,	18	statement?
19	somewhere between 21 and 28 let's call	19	A Present on like the
20	that 25 days, and Liebert saw induction in	20	Q Present at the mesh, present at the tissues.
21	vivo at around 100 days.	21	A Per area of something like this, right?
22	That tells us that events are happening	22	Q Per the same area?
23	in our in vitro test about four times faster	23	A Yeah. I mean, I think this is equivalent to
24	than they happen in that in vivo hamster	24	what I said. If you have more macrophages
25	model, which is a subcutaneous suture	25	per area, more foreign body giant cells, that

37 (Pages 142 to 145)

	Page 146		Page 148
1	is a factor. I mean, certainly that's a	1	things as well.
2	factor.	2	I would rather say that there is lots of
3	But, again, I want to emphasize that the	3	factors that can affect this. And it's
4	point of the tests was not to calculate the	4	basically accelerated by it happens about
5	rate of at which through the time at which	5	four times faster than what Liebert observed
6	induction happens. It was just to answer	6	in that hamster model. I can say that. But
7	this question, can it oxidize, can it become	7	how many macrophages, I we don't know how
8	induced, can it degrade. That was the	8	many macrophages Liebert observed. So it's
9	purpose of the tests.	9	very difficult to calibrate it to that level
10	So we were not trying to say use these	10	of detail.
11	data to calculate the induction time of	11	Does that make
12	Prolene mesh in the vaginal space. There	12	Q I guess maybe if I can back up and just make
13	were a number of factors affecting this. All	13	this question as simple as possible.
14	this test shows is that it happens. It can	14	A Okay. Yeah.
15	oxidize and degrade. That was the purpose.	15	Q Are there any documents that are in those
16	Q What is the size of the solution that you put	16	test files that say for this solution, for a
17	the single TVT device in?	17	given amount of the solution, that is the
18	A These were vials. I don't know. Maybe 20	18	equivalent to the hydroxl radicals that can
19	milliliter vials. I can't remember the size	19	be produced by Y number of macrophages?
20	of them. They were maybe that tall and maybe	20	A I don't know that that correlation exists. I
21	that big around (indicating). They were	21	don't know.
22	vials.	22	MR. SNELL: Okay. Let's take a
23	Q So you put a piece of the mesh in the vial,	23	break.
24	and the vial had the solution?	24	(A brief recess is taken from
25	A Yes.	25	3:25 to 3:45 p.m.)
	Page 147		Page 149
1	O Were all of the vials filled with the same	1	(Denosition Exhibit No. 3 is
1 2	Q Were all of the vials filled with the same amount of solution?	1 2	(Deposition Exhibit No. 3 is
2	amount of solution?	2	marked for identification.)
2 3	amount of solution? A Yes. I believe those I can't remember the	2	marked for identification.) BY MR. SNELL:
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2 3 4 5 6	amount of solution? A Yes. I believe those I can't remember the number, but Dr. Dunn controlled for that. Q As you sit here, do you know how much solution was put in each bottle?	2 3 4 5 6	marked for identification.) BY MR. SNELL: Q Dr. Guelcher, we are back on the record. We have marked as Exhibit 3, the thumb drive, that has the different documents, reliance
2 3 4 5 6 7	 amount of solution? A Yes. I believe those I can't remember the number, but Dr. Dunn controlled for that. Q As you sit here, do you know how much solution was put in each bottle? A I don't remember the number. It was in the 	2 3 4 5 6 7	marked for identification.) BY MR. SNELL: Q Dr. Guelcher, we are back on the record. We have marked as Exhibit 3, the thumb drive, that has the different documents, reliance materials, etc., that you brought to the
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2 A That's correct: 3 Q Now, within that in vitro testing folder, there are additional subfolders, correct? 4 That's correct. 5 A That's correct. 6 Q All right. So where is the study protocol? 7 A Okay. Tm going to have to look for that. 8 MR, KUNTZ: Again, there is a folder called protocols. 9 Folder called protocols. 10 MR, SNELL: I hear you. I just want the witness to tell me that it's actually in there and show me where it is. 11 a Tm looking. Okay. Study design and protocols. There is a folder called study design and protocols. There is a folder called study design and protocols. There is a folder called study design and protocols. There is a folder called study design and protocols. 16 BY MR, SNELL: 17 Q Okay. Give me a second. I'm in the study design and protocols folder. And where is the study protocol? 18 A Okay. There is — I believe it's the oxidative media Preparation file. Let me look at that and I believe that is it. So that that and I believe that is it. So that would be — and then he has notes on what he did. So it's 5 mils, approximately 5 milliliters of whe media, of solution? 19 A I don't remember the number that he used or that used in my papers. I don't remember that I used in my papers. I don't remember that I used in my papers. I don't remember that I used in my papers. I don't remember that I was calling the SoP. It says, and the solution. 10 Q and how much is put into each of the vials? 11 A I will have to look at a different procedure, because I think this is just the master solution. 22 Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? 23 A That's my graduate student, Anne Talley, She is the one who has been maintaining this draft that I have approved. 24 You asked about what, how much is added, the volume? 25 Q Who is ADT? 26 A That's my graduate student, Anne Talley, She is the one who has been maintaining this draft that I have approved. 29 Yes, the volume added to the vial of the same than all of the sample mumbers are liked the care that. Th	1	nolypropylene pellet?	1	for that
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prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? Let me find it. Referent procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A That's my graduate student, Anne Talley. She is the one who has been maintaining this draft that I have approved. You asked about what, how much is added, the volume? Q Yes, the volume added to the vial of the solution. I approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail. We did discuss this. The Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail. The Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail. The Anderson paper specified this level of detail. That I remember, but I would have to confirm that I remember. We discussed this test. I don't remember. We discussed this test. I don't remember. We discussed this test. I don't rem	25	oxidative media preparation. This is how we	25	Q Did Dr. Dunn decide the procedure to use
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4 cobalt chloride hexahydrate, 30-percent 5 hydrogen peroxide solution and water. And 6 these materials are mixed to make the 1 liter 7 master batch, and the procedures are all 8 listed here for that. That is how we get the 9 solution. 10 Q And how much is put into each of the vials? 11 A I will have to look at a different procedure, 12 because I think this is just the master 13 batch. Let me find it. 14 Q Before you leave that document, at the bottom 15 left it says, ADT dash last edit 9/15/14? 16 A Yes. 17 Q Who is ADT? 18 A That's my graduate student, Anne Talley. She 19 is the one who has been maintaining this 20 draft that I have approved. 21 You asked about what, how much is added, the volume? 22 Q Yes, the volume added to the vial of the 24 specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that I remember, but I would have to confirm that I remember, but I would have to confirm that I remember, but I would have to confirm that I remember, but I would have to confirm that I remember, but I would have to confirm that I remember. Do you want me to do that? 10 Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember. I know I'm trying to find this. Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. Q Let me just ask the question again. Who decided to use approximately 5 milliliters of oxidated media to be put in into each vial? A I know we discussed this, but I don't remember the details. We discussed all of	1		1	
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master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A That's my graduate student, Anne Talley. She is the one who has been maintaining this draft that I have approved. You asked about what, how much is added, the volume? Q Yes, the volume added to the vial of the solution. That I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? That I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? That I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? A I don't remember. We discussed this test. I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this. Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. Q Let me just ask the question again. Who decided to use approximately 5 milliliters of oxidated media to be put in into each vial? A I know we discussed this, but I don't remember the details. We discussed all of	2	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2,	2 3	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did
listed here for that. That is how we get the solution. Q And how much is put into each of the vials? I A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A Yes. Q Who is ADT? A That's my graduate student, Anne Talley. She is the one who has been maintaining this draft that I have approved. You asked about what, how much is added, the volume? Q Yes, the volume added to the vial of the solution. I that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this. Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. Q Let me just ask the question again. Who decided to use approximately 5 milliliters of oxidated media to be put in into each vial? A I know we discussed this, but I don't remember the details. We discussed all of	2 3 4	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent	2 3 4	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did
9 solution. 10 Q And how much is put into each of the vials? 11 A I will have to look at a different procedure, 12 because I think this is just the master 13 batch. Let me find it. 14 Q Before you leave that document, at the bottom 15 left it says, ADT dash last edit 9/15/14? 16 A Yes. 17 Q Who is ADT? 18 A That's my graduate student, Anne Talley. She 19 is the one who has been maintaining this 20 draft that I have approved. 21 You asked about what, how much is added, 22 the volume? 23 Q Yes, the volume added to the vial of the 24 solution. 29 to do that? 10 Q Who was it who decided to use 5 milliliters 11 of oxidated media in each file? 12 A I don't remember. We discussed this test. I 13 don't remember discussing where exactly that 14 came from. I know I'm trying to find 15 this. 16 Okay. Is there a question? What was the 17 question? I don't remember. I thought I 18 answered it, but I will answer it again. 19 Q Let me just ask the question again. Who 19 decided to use approximately 5 milliliters s 20 of oxidated media to be put in into each 21 vial? 22 Ves, the volume added to the vial of the 23 A I know we discussed this, but I don't 24 remember the details. We discussed all of	2 3 4 5	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And	2 3 4 5	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not
9 solution. 10 Q And how much is put into each of the vials? 11 A I will have to look at a different procedure, 12 because I think this is just the master 13 batch. Let me find it. 14 Q Before you leave that document, at the bottom 15 left it says, ADT dash last edit 9/15/14? 16 A Yes. 17 Q Who is ADT? 18 A That's my graduate student, Anne Talley. She 19 is the one who has been maintaining this 20 draft that I have approved. 21 You asked about what, how much is added, 22 the volume? 23 Q Yes, the volume added to the vial of the 24 solution. 29 to do that? 10 Q Who was it who decided to use 5 milliliters 11 of oxidated media in each file? 12 A I don't remember. We discussed this test. I 13 don't remember discussing where exactly that 14 came from. I know I'm trying to find 15 this. 16 Okay. Is there a question? What was the 17 question? I don't remember. I thought I 18 answered it, but I will answer it again. 19 Q Let me just ask the question again. Who 19 decided to use approximately 5 milliliters s 20 of oxidated media to be put in into each 21 vial? 22 Ves, the volume added to the vial of the 23 A I know we discussed this, but I don't 24 remember the details. We discussed all of	2 3 4 5 6	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter	2 3 4 5 6	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail
10 Q And how much is put into each of the vials? 11 A I will have to look at a different procedure, 12 because I think this is just the master 13 batch. Let me find it. 14 Q Before you leave that document, at the bottom 15 left it says, ADT dash last edit 9/15/14? 16 A Yes. 17 Q Who is ADT? 18 A That's my graduate student, Anne Talley. She 19 is the one who has been maintaining this 20 draft that I have approved. 21 You asked about what, how much is added, 22 the volume? 23 Q Yes, the volume added to the vial of the 24 solution. 20 Who was it who decided to use 5 milliliters 21 of oxidated media in each file? 22 A I don't remember. We discussed this test. I 23 don't remember discussing where exactly that 24 came from. I know I'm trying to find 25 this. 26 Okay. Is there a question? What was the 27 question? I don't remember. I thought I 28 answered it, but I will answer it again. 29 Q Let me just ask the question again. Who 20 decided to use approximately 5 milliliters s 21 of oxidated media to be put in into each 22 vial? 23 A I know we discussed this, but I don't 24 remember the details. We discussed all of	2 3 4 5 6 7	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all	2 3 4 5 6 7	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm
11 A I will have to look at a different procedure, 12 because I think this is just the master 13 batch. Let me find it. 14 Q Before you leave that document, at the bottom 15 left it says, ADT dash last edit 9/15/14? 16 A Yes. 17 Q Who is ADT? 18 A That's my graduate student, Anne Talley. She 19 is the one who has been maintaining this 20 draft that I have approved. 21 You asked about what, how much is added, 22 the volume? 23 Q Yes, the volume added to the vial of the 20 sefore you leave that document, at the bottom 12 A I don't remember. We discussed this test. I 23 don't remember discussing where exactly that 24 came from. I know I'm trying to find 25 this. 26 Okay. Is there a question? What was the 27 question? I don't remember. I thought I 28 answered it, but I will answer it again. 29 Q Let me just ask the question again. Who 20 decided to use approximately 5 milliliters s 21 of oxidated media to be put in into each 22 vial? 23 Q Yes, the volume added to the vial of the 24 solution. 24 solution. 25 A I know we discussed this, but I don't 26 remember the details. We discussed all of	2 3 4 5 6 7 8	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the	2 3 4 5 6 7 8	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me
because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A Yes. Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. A That's my graduate student, Anne Talley. She is the one who has been maintaining this odraft that I have approved. You asked about what, how much is added, the volume? Q Yes, the volume added to the vial of the solution. A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this. Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. Q Let me just ask the question again. Who decided to use approximately 5 milliliters s of oxidated media to be put in into each vial? A I know we discussed this, but I don't remember the details. We discussed all of	2 3 4 5 6 7 8	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution.	2 3 4 5 6 7 8 9	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that?
batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A Yes. Q Who is ADT? A That's my graduate student, Anne Talley. She is the one who has been maintaining this draft that I have approved. You asked about what, how much is added, the volume? Q Yes, the volume added to the vial of the solution. 13 don't remember discussing where exactly that came from. I know I'm trying to find this. 14 came from. I know I'm trying to find this. 15 don't remember discussing where exactly that came from. I know I'm trying to find this. 16 Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. 19 Q Let me just ask the question again. Who decided to use approximately 5 milliliters solution of oxidated media to be put in into each vial? 21 A I know we discussed this, but I don't remember the details. We discussed all of	2 3 4 5 6 7 8 9	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials?	2 3 4 5 6 7 8 9	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters
14 Q Before you leave that document, at the bottom 15 left it says, ADT dash last edit 9/15/14? 16 A Yes. 17 Q Who is ADT? 18 A That's my graduate student, Anne Talley. She 19 is the one who has been maintaining this 20 draft that I have approved. 21 You asked about what, how much is added, the volume? 22 Q Yes, the volume added to the vial of the solution. 24 came from. I know I'm trying to find 15 this. 16 Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. 19 Q Let me just ask the question again. Who decided to use approximately 5 milliliters solution. 21 of oxidated media to be put in into each vial? 22 Vial? 23 Q Yes, the volume added to the vial of the solution. 24 remember the details. We discussed all of	2 3 4 5 6 7 8 9 10	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure,	2 3 4 5 6 7 8 9 10	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file?
15 left it says, ADT dash last edit 9/15/14? 16 A Yes. 17 Q Who is ADT? 18 A That's my graduate student, Anne Talley. She 19 is the one who has been maintaining this 20 draft that I have approved. 21 You asked about what, how much is added, the volume? 22 Q Yes, the volume added to the vial of the solution. 25 slotting this. 26 Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. 26 Q Let me just ask the question again. Who decided to use approximately 5 milliliters solution. 27 of oxidated media to be put in into each vial? 28 Q Yes, the volume added to the vial of the solution. 29 A I know we discussed this, but I don't remember the details. We discussed all of	2 3 4 5 6 7 8 9 10 11 12	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master	2 3 4 5 6 7 8 9 10 11 12	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I
16 A Yes. 17 Q Who is ADT? 18 A That's my graduate student, Anne Talley. She 19 is the one who has been maintaining this 20 draft that I have approved. 21 You asked about what, how much is added, 22 the volume? 23 Q Yes, the volume added to the vial of the 24 solution. 26 Okay. Is there a question? What was the 27 question? I don't remember. I thought I 28 answered it, but I will answer it again. 29 Q Let me just ask the question again. Who 20 decided to use approximately 5 milliliters s 21 of oxidated media to be put in into each 22 vial? 23 A I know we discussed this, but I don't 24 remember the details. We discussed all of	2 3 4 5 6 7 8 9 10 11 12 13	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it.	2 3 4 5 6 7 8 9 10 11 12 13	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that
17 Q Who is ADT? 18 A That's my graduate student, Anne Talley. She 19 is the one who has been maintaining this 20 draft that I have approved. 21 You asked about what, how much is added, 22 the volume? 23 Q Yes, the volume added to the vial of the 24 solution. 21 question? I don't remember. I thought I 28 answered it, but I will answer it again. 29 Q Let me just ask the question again. Who 20 decided to use approximately 5 milliliters s 21 of oxidated media to be put in into each 22 vial? 23 A I know we discussed this, but I don't 24 remember the details. We discussed all of	2 3 4 5 6 7 8 9 10 11 12 13 14	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom	2 3 4 5 6 7 8 9 10 11 12 13 14	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find
A That's my graduate student, Anne Talley. She is the one who has been maintaining this draft that I have approved. You asked about what, how much is added, the volume? Q Let me just ask the question again. Who decided to use approximately 5 milliliters s of oxidated media to be put in into each vial? Q Yes, the volume added to the vial of the solution. A I know we discussed this, but I don't remember the details. We discussed all of	2 3 4 5 6 7 8 9 10 11 12 13 14 15	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this.
19 is the one who has been maintaining this 20 draft that I have approved. 21 You asked about what, how much is added, 22 the volume? 23 Q Yes, the volume added to the vial of the 24 solution. 29 Q Let me just ask the question again. Who 20 decided to use approximately 5 milliliters s 21 of oxidated media to be put in into each 22 vial? 23 A I know we discussed this, but I don't 24 remember the details. We discussed all of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this. Okay. Is there a question? What was the
draft that I have approved. You asked about what, how much is added, the volume? Q Yes, the volume added to the vial of the solution. 20 decided to use approximately 5 milliliters s 21 of oxidated media to be put in into each 22 vial? 23 A I know we discussed this, but I don't 24 remember the details. We discussed all of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A Yes. Q Who is ADT?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this. Okay. Is there a question? What was the question? I don't remember. I thought I
You asked about what, how much is added, the volume? 21 of oxidated media to be put in into each vial? 22 vial? 23 Q Yes, the volume added to the vial of the solution. 21 of oxidated media to be put in into each 22 vial? 23 A I know we discussed this, but I don't 24 remember the details. We discussed all of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A Yes. Q Who is ADT? A That's my graduate student, Anne Talley. She	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this. Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again.
22 the volume? 23 Q Yes, the volume added to the vial of the 24 solution. 22 vial? 23 A I know we discussed this, but I don't 24 remember the details. We discussed all of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A Yes. Q Who is ADT? A That's my graduate student, Anne Talley. She is the one who has been maintaining this	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this. Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. Q Let me just ask the question again. Who
23 Q Yes, the volume added to the vial of the 23 A I know we discussed this, but I don't 24 remember the details. We discussed all of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A Yes. Q Who is ADT? A That's my graduate student, Anne Talley. She is the one who has been maintaining this draft that I have approved.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this. Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. Q Let me just ask the question again. Who decided to use approximately 5 milliliters s
24 solution. 24 remember the details. We discussed all of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A Yes. Q Who is ADT? A That's my graduate student, Anne Talley. She is the one who has been maintaining this draft that I have approved. You asked about what, how much is added,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this. Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. Q Let me just ask the question again. Who decided to use approximately 5 milliliters s of oxidated media to be put in into each
	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A Yes. Q Who is ADT? A That's my graduate student, Anne Talley. She is the one who has been maintaining this draft that I have approved. You asked about what, how much is added, the volume?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this. Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. Q Let me just ask the question again. Who decided to use approximately 5 milliliters s of oxidated media to be put in into each vial?
	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	prepared the medium that you were asking me about. So it has the recipe for it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution. Q And how much is put into each of the vials? A I will have to look at a different procedure, because I think this is just the master batch. Let me find it. Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14? A Yes. Q Who is ADT? A That's my graduate student, Anne Talley. She is the one who has been maintaining this draft that I have approved. You asked about what, how much is added, the volume? Q Yes, the volume added to the vial of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	approximately 5 milliliters of oxidated media in each file? A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that? Q Who was it who decided to use 5 milliliters of oxidated media in each file? A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know I'm trying to find this. Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again. Q Let me just ask the question again. Who decided to use approximately 5 milliliters s of oxidated media to be put in into each vial? A I know we discussed this, but I don't

39 (Pages 150 to 153)

	Page 154		Page 156
1	any more details than that.	1	something that Dr. Dunn did?
2	Q The same number of samples of unstabilized	2	A I can't remember the details of that decision
3	polypropylene control were not used as the	3	right now.
4	TVT; is that correct?	4	Q Who made the decision to only use 15 samples
5	A I need to look at the spreadsheet again.	5	of the unstabilized polypropylene but 36
6	Polypropylene standard you say the same	6	samples of the TVT?
7	why I don't see that. Where are you	7	A I don't remember those details either.
8	looking?	8	Q When you do statistical analyses comparing
9	Q I'm looking at the Excel file you pointed out	9	the unstabilized polypropylene to the TVT,
10	at above PP standard. Let's just make sure.	10	don't you have to take into account
11	Is the PP standard, is that the unstabilized	11	differences in sample sizes and differences
12	polypropylene control?	12	in the quantity of time points analyzed?
13	A Yes. And to get back to one of your previous	13	A Yeah, for comparing between for comparing
14	questions, the MSDS and the supplier for that	14	between groups, those factors would have to
15	material is here.	15	be taken into account, but I just don't
16	Q And so for the unstabilized polypropylene	16	remember the details of that study design.
17	control, there were only 15 samples, correct?	17	Q Who did the FTIR testing?
18	A Oh, I see the top of the column, 15 samples.	18	A Dr. Dunn.
19	That's probably because it became oxidized	19	Q He personally did it or did he have somebody
20	more quickly. I don't so we only went out	20	else do it?
21	to four weeks with the because it became	21	A I believe he did it. But, again, it was done
22	induced faster, the 15 samples. I don't know	22	through his company, so I don't know the
23	the answer to that now, what the number of	23	details of who actually did what
24	replicates for each time point was. I can't	24	measurements, but I believe he did it.
25	tell from this table.	25	Q Do you know where this FTIR machine was that
	Page 155		Page 157
1	Q Why were there only 15 samples of the	1	was used in this test?
2	unstabilized polypropylene control, but 36	2	A Yes. It's in his laboratory.
3	samples of the TVT?	3	Q So he used the Vanderbilt lab FTIR machine
4	A Well, one reason would be because we didn't	4	for the test?
5	do as many time points. We did four weeks,	5	A Well, I would say he used the FTIR in his
6	it looks like, instead of and I don't	6	laboratory at Vanderbilt.
7	think that we did as much I spoke	7	Q Did he buy that FTIR machine?
8	incorrectly. I think previously it appears	8	A He would have to speak to the details of
9	that we actually had separate samples for XPS	9	that.
10	and FTIR, and it doesn't look like we had as	10	Q I guess the question is you took issue
11	many XPS samples. I would have to think	11	with whether I asked you do you know who
12	about that.	12	owns that FTIR machine? Is it Vanderbilt or
13	Q Do you know why you only analyzed the	13	Dr. Dunn or
14	unstabilized polypropylene control out to	14	A I don't know the details of that. When you
15	four weeks, whereas you analyzed the TVT	15	said the Vanderbilt lab, that was, I thought,
16	later?	16	a little vague. I wanted to clarify that it
17	A It became induced faster, so the unstabilized	17	was it's in his laboratory space that he
18	control became induced between weeks three	18	has been assigned at Vanderbilt.
19	and four. So we didn't do as many time	19	Q Okay.
20	limits.	20	A That's what I meant.
21	Q You could have still tested it, though, at	21	Q All right. But it very well could be that
22	five and six weeks, right?	22	that is a machine that is actually owned by
23	A We could have.	23	Vanderbilt?
24	Q Did you make an affirmative decision not to	24	A I don't know the details. As I said,
25	test at four and five weeks or is that	25	Dr. Dunn has an agreement with the

40 (Pages 154 to 157)

	Page 158		Page 160
1	university. That's all I know. He would	1	expertise. She has a lot of experience with
2	have to speak as to the rest of it.	2	it.
3	Q Now, the SEM analysis, whose SEM machine was	3	Q Is Dr. Rogers an expert for plaintiffs in
4	used?	4	transvaginal mesh litigation that you're
5	A There is an SEM instrument and it's an	5	aware of?
6	institutional resource. It's a shared	6	A Not to my knowledge. She was contracted by
7	resource is perhaps a better way of saying	7	Dr. Dunn to do the work.
8	it, and so we pay for machine time.	8	Q Do you know how much she was paid by
9	Q Is it located at Vanderbilt?	9	Dr. Dunn?
10	A It is.	10	A I don't know the details of that. Probably
11	Q In what school?	11	the same as my arrangement, but I don't know.
12	A Well, it's an institute, so it's between	12	Q Was she aware of Dr. Dunn's role as an expert
13	schools and the members of the school of	13	in transvaginal mesh litigation?
14	engineering, college of arts and science,	14	A Yes, she was, to my knowledge.
15	medicine. It's a shared resource.	15	Q She is aware that Dr. Dunn is being paid by
16	Q It's not in Dr. Dunn's lab?	16	attorneys for plaintiffs in transvaginal mesh
17	A No.	17	litigation?
18	Q Physically where is it? Is it within a	18	A I believe she would.
19	building in the department of medicine?	19	Q So when she sat down to do this XPS analysis,
20	Department of engineering?	20	she knew that the money was coming from
21	A Again, it's a building that has shared space	21	plaintiffs' lawyers in transvaginal mesh
22	between the college of arts and science and	22	litigation?
23	the school of engineering.	23	A Yes, I believe she knew that. I haven't
24	Q Who did the SEM images?	24	I'm hesitating because I can't remember
25	A Again, it was Dr. Dunn's company. Whether he	25	explicitly discussing that with her, but I
	Page 159		Page 161
1	had an employee doing that, I don't know. He	1	believe based on conversations with Russell
2	was responsible for all of that.	2	that she knew she was being paid by
3	Q The XPS machine that was used to look at the	3	litigation.
4	sample, where is that machine?	4	Q Did Dr. Dunn have a conversation with
5	A So that machine is also administered by the	5	Dr. Rogers about doing this XPS testing?
6	institute I was referring to earlier. It's	6	A Yes.
7	housed in the laboratory of Professor Bridget	7	Q Were you present at the time of that
8	Rogers. So to clarify just for the record	8	conversation?
9	one of the earlier questions about who else	9	A For some of the conversations, we did discuss
10	at Vanderbilt was involved, Professor Bridget	10	it as a group with Professor Rogers. Was I
11	Rogers is a professor, an associate professor	11	there for every conversation, I can't say
12	of chemical and biomolecular engineering, and	12	that I was. I did discuss this with
13	she did the XPS testing.	13	Professors Dunn and Rogers.
14	That slipped my mind earlier, I'm sorry,	14	Q And what was said?
15	until we talked about it now.	15	A Well, we discussed how to do the analysis,
16	Q So Dr. Rogers was actually the one who did	16	what we were looking for, how we wanted to do
17	the XPS testing on this single TVT retropubic	17	the experiment, and what the goal was. We
18	device and the unstabilized polypropylene	18	discussed the approach for the measurements.
19	control?	19	Q Who paid for the SEM time?
20	A She did.	20	A Again, I can't answer that oh, for the
21	Q Were you there when she did the testing?	21	SEM. I'm sorry. I believe that Dr. Dunn has
22	A No, but I don't need to be there when she	22	a sponsor research agreement through the
23	it's a she ran it and	23	university in which he set up a cost center.
24	Q Why didn't you do the XPS testing?	24	But, again, he has to speak to all of this.
25	A That's Dr. Rogers' particular area of	25	I believe it was paid for by the litigation

41 (Pages 158 to 161)

	Page 162		Page 164
1	through a center number from the university.	1	Q These aren't the same pellets that are used
2	Q What do you mean by center number?	2	in the TVT device, correct?
3	A Well, when we do internal billing within the	3	A Not to my knowledge.
4	university, we have cost centers associated	4	Q What is isotactic polypropylene?
5	with different funding sources. So he would	5	A That is just a reference to the structure of
6	have used the cost center associated with his	6	the polypropylene. Most polypropylene is
7	sponsored research agreement. But, again, I	7	sold commercially. And my understanding is
8	am hesitant to go it's his project. I	8	isotactic is the most common isomer. I will
9	don't know the details of that.	9	say to my knowledge that polypropylene used
10	Q Who paid Dr. Rogers for her time?	10	to make Prolene is also isotactic, if that
11	A Dr. Dunn. She invoiced Dr. Dunn, and then	11	helps.
12	Dr. Dunn invoiced plaintiff's counsel.	12	Q Are you certain of that?
13	Q How much did Dr. Rogers' invoice in	13	A Pretty certain. I believe that's the case.
14	connection with this test that you're relying	14	Q Section 9 has different physical and chemical
15	on?	15	properties of this unstabilized polypropylene
16	A I don't know the answer to that.	16	control?
17	Q Do you know how much Dr. Dunn has invoiced in	17	A Section 9, yes.
18	connection with this test that you're relying	18	Q Do you know if these properties are in any
19	on?	19	way different than the polypropylene pellets
20	A I haven't seen his invoices. I don't know.	20	that are used in the TVT device?
21	Q Would it be based on your understanding more	21	A Could you ask that again? I didn't catch it.
22	than \$50,000 as an accurate prediction?	22	Q Sure.
23	A I don't know. I can't put a number on it	23	For the chemical and physical properties
24	because I didn't see the invoices.	24	of the unstabilized polypropylene control
25	Q For the use of the XPS machine, am I correct	25	that you used, are you aware if the
	Page 163		Page 165
1	that someone would have to pay for that time	1	properties are any different than the same
2	or usage as well?	2	properties for the pellets that are
3	A I don't know the details of that arrangement	3	specifically used in the TVT device?
4	with the XPS with Dr. Rogers. I can't speak	4	A These properties appear to me to be very
5	to that.	5	similar. If I'm looking at Sections 9 and
6	Q The unstabilized polypropylene control, is	6	10, the melting point of 160 degrees. This
7	that contained within the file that says	7	is the melting point I remember for Prolene
8	polypropylene standard MSDS?	8	from some of the internal documents, the
9	A You were interested about the source?	9	saline water is negligible.
10	Q Yes.	10	If we look at stability and reactivity,
11	A Yes, I believe that it is, and I'm going to	11	it also says materials to avoid, oxidizing
12	look at it right now. So this is the file,	12	materials. It looks very much like something
13	polypropylene standard MSDS, and I'm clicking	13	I would see for the MSDS for the
14	on this link.	14	polypropylene used to make Prolene that I
15	Okay. This is an MSDS. I believe it is	15	saw. So to answer to your question, I would
16	the polypropylene standard. If you see the	16	say it looks similar to me.
17	ingredient, it says isotactic polypropylene	17	Q And for the SEM test results that you
18	at 100 percent. So this would be the	18	A Did you open the file? Is that where you
19	unstabilized polypropylene control. It was	19	are?
20	purchased from Scientific Polymer Products,	20	Q Yeah, I was going to ask you. The SEM test
21	Incorporated, and that would be the MSDS for	21	results you believe showed pitting and you
22	that material.	22	said peeling. Would those be found in that
	Q And this is the pellets that you were talking	23	folder PCT-168SEM?
23		2/	A I'm looking CEM was
23 24 25	about? A Yes.	24 25	A I'm looking. SEM, yes. Did you have a question or

42 (Pages 162 to 165)

	Page 166		Page 168
1	Q I am just trying to see, are the SEM images	1	Q This does not show anything like that,
2	that you referenced in that file PCT-168SEM?	2	correct?
3	A I'm looking at a file TVT five week SEM PDF.	3	A We don't see the cracking because we did not
4	I'm not sure what you're asking me. If you	4	apply these materials are not under
5	can just ask me again what you're looking	5	tension. There is no residual strain. So in
6	for.	6	the Anderson paper 1993, they prestressed the
7	Q The particular SEM images that you referenced	7	materials. And when they did this and
8	that you be believed showed pitting or the	8	they incubated them in an oxidative medium.
9	peeling?	9	When they did this, they were able to see
10	A Yes.	10	environmental stress cracking.
11	MR. KUNTZ: I will object. But	11	We did not prestress the materials.
12	go ahead.	12	Again, the question was really to answer can
13	A Okay. So I'm looking at this. I'm in this	13	it oxidize. So without that mechanical
14	SEM directory. I'm clicking On TVT five	14	stress, we see more of these effects of
15	weeks. There is a folder called TVT five	15	peeling and blistering. And this is
16	weeks, and I believe these are individual	16	described in a number of papers to see
17	files. And then I believe this file TVT SEM,	17	environmental stress cracking you need a
18	TVT five weeks SEM PDF, I believe that that	18	combination of three things. One is an
19	is the file I was talking about earlier.	19	oxidative medium, the second is a material
20	So when I open this file, I see a number	20	that degrades in response to that medium, and
21	of SEM images of PET that show that there is	21	the third is mechanical stress.
22	a pitting and flaking on the surface of the	22	So that there is no mechanical stress
23	TVT. That's what I was describing earlier.	23	in this experiment, which would be why I
24	BY MR. SNELL:	24	don't believe we were seeing the transverse
25	Q On the second photo can you look at my	25	cracking as noticed in Clave and other
	Page 167		Page 169
1	computer?	1	papers.
2	A The second photo is called PCT168SEM007.	2	Q Isn't another just as plausible answer that
3	Q Yes, that's what I'm looking at.	3	there is no proteins and biofilm on these
4	A Okay.	4	images?
5	Q And towards the middle, that's a fiber that	5	A Not in my opinion.
6	we're looking at?	6	Q Let me ask you, were proteins and biofilm
7	A Yes, that's a specific fiber.	7	actually put on your samples of the TVT
8	Q Take a look towards the middle at the bottom,	8	device?
9	if you can look at what I'm looking at.	9	A So I want to be specific about this term
10	Right here.	10	biofilm. Biofilm is a polysaccharide matrix.
11	A Yes.	11	It's deposited by bacteria. To me that's
12	Q Right above the times 400.	12	different than protein absorption. And I'm
13	A Yes.	13	not aware of papers that are saying protein
14	Q And then moving directly north in the middle	14	absorption is causing cracking. I mean, but
15	here. What is that?	15	the biofilm to me is the polysaccharide
16	A That looks to me like an area that I would	16	matrix deposited by bacteria.
17	call degradation, where the surface is	17	Protein absorption is something
18	changing. It looks like there is some	18	different, but it I mean, the surface is
19	pitting and some residue, blistering perhaps.	19	degrading here is what I see in response to
20	That looks like an area of surface	20	the chemical induction is how I interpret
21	degradation.	21	these events.
22	Q In the SEM photos that I've seen in the	22	Q There is no cracking in your photos of the
23	literature, those typically show cracks	23	SEMs similar to those seen in the body as in
24	running horizontal, correct?	24	Clave and Costello and de Tayrac, correct?
25	A That's right.	25	A Again, there is no cracking here because

43 (Pages 166 to 169)

	Page 170		Page 172
1	these materials were not under any mechanical	1	show the cracks. And then after they have
2	stress. There was no force. They weren't	2	cleaned off the biofilm, you know, it was
3	pre-strained like in the '93 Anderson paper.	3	clear that the filaments were fine?
4	This is a protocol that was used in the '97	4	A Yes, but I think this is a different
5	Anderson paper to answer the question of	5	question. I agree with what that paper is
6	oxidation. We didn't have mechanical	6	saying in that we can pull it up and look
7	strengths, and that's why we're not seeing	7	at it again. I'm going on my memory, but I
8	cracking.	8	think it was only 30 days. And I have done
9	Q You would agree that another plausible	9	these experiments myself. I've contaminated
10	explanation for why you don't see cracking is	10	scaffolds and placed them in I just
11	there was no biofilm used in your testing?	11	published a paper on this last year we
12	MR. KUNTZ: Objection.	12	placed it in a bone defect.
13	A I don't agree with that.	13	We come back four weeks later, and we see
14	BY MR. SNELL:	14	a biofilm, and it looks a lot like that
15	Q Have you seen anywhere in the literature	15	biofilm. And they clean it off, and, yeah,
16	during your analyses where cracking was seen	16	there is no damage to the polypropylene
17	on an explant, and upon cleaning the explant,	17	because it was only 30 days. It was a very
18	it was determined that biofilm was the source	18	short period of time. And as we've been
19	of the cracking? First of all, have you seen	19	discussing from Liebert and some of these
20	that in the literature?	20	other papers, we wouldn't scientifically,
21	MR. KUNTZ: Objection. Go	21	polypropylene would be induced at around 100
22	ahead.	22	days.
23	A I believe the paper you're talking about that	23	So it's not too surprising to me that in
24	I've seen was and correct me if I'm	24	30 days, the polypropylene hasn't started to
25	describing the wrong paper, but I have seen a	25	crack yet. That's a very early time point.
	Page 171		Page 173
1	paper where the mesh was challenged with	1	That's the way I understand that paper. But,
2	bacteria. We have a contaminated mesh. And	2	again, I would be happy talk about it with
3	then the SEM images I saw this is only 30	3	you, but that's my memory of that paper.
4	days, and this SEM image showed what appeared	4	Q Do we know how much the Prolene polypropylene
5	to be a biofilm, which I would expect,	5	is induced at 120 days?
6	because it was challenged with bacteria, and	6	A I think I know what you're getting at, but I
7	that biofilm showed cracks. But it looked	7	would like you to ask it a different way.
8	like a biofilm. It didn't look like the SEM	8	Induction time, it's an event, so we can't
9	images in Clave. And some of the other	9	say how much it's induced. We can say either
10	explanted mesh papers don't look like	10	it's become induced or it has not. So are
11	biofilms to me.	11	you asking I guess I'm not sure what
12	We can look at that paper. It's in my	12	you're asking.
13	reliance materials. I can look for it, but I	13	Q What is the significance of induction?
14	believe that's the paper you're referring to,	14	A So it's described in many of my reliance
15	and I have considered that. I believe that's	15	materials. But an induction just to think
16	a biofilm. And if you wash that biofilm off,	16	of a plot, we see a small change in
17	it goes away, and there is no damage to	17	properties. So it's oxidizing, because there
18	underlying substrate, because it's only 30	18	is adherent macrophages in giant cells, and
19	days. And so these events may not have	19	it's oxidizing.
20	started happening yet, because 30 days is a	20	And then we reach this point where the
	relative short period of time. That's my	21	reaction becomes autocatalytic, and there is
21			
22	explanation of the paper that I believe	22	a very strong increase in the slope, kind of
22 23	explanation of the paper that I believe you're referring to.	23	like hockey-stick applied. And that change
22	explanation of the paper that I believe		

44 (Pages 170 to 173)

			Page 176
1	So to say how much it is induced, I'm	1	Q Under PCT 168 XPS
2	I'm trying to explain why I can't answer that	2	A Oh, you're on the XPS now.
3	question.	3	Q I'm in a Document 11062014 PCT 168 report.
4	Q When does that chemical induction time take	4	A Are you looking at the XPS report?
5	place with the Prolene polypropylene?	5	
6	A We talked about this earlier. It's difficult	6	Q Yes. This is actually from Bridget Rogers. A Okay. I am pulling up the report.
7		7	Q On the second page, table one, it says
8	to when that happens in the body is going	8	
9	to be affected by a number of factors. But	9	fraction of carbon atoms bonded in the RCOOH
10	it's I think it's unlikely that that would	10	and the CO configuration?
11	happen in 30 days. That's very early. And		A Right.
12	that's why I explained the biofilm it	11	Q What is that RCOOH?
	could happen maybe in some conditions in 30	12	A So RCOOH is the hydroperoxide group that's
13	days, but I don't believe in that experiment.	13	formed when the polypropylene is oxidized.
14	Q Is there a certain point in which it becomes	14	It's an intermediate in that complex reaction
15	significant?	15	mechanism.
16	A What becomes significant?	16	Q And what does it mean when there is zeros in
17	Q This induction.	17	this table?
18	A Well, it's an event. So at induction, there	18	A So if it's a zero, that means that in that
19	is dramatic changes in physical properties.	19	particular spot she was looking at under the
20	But embrittlement in these events can happen	20	microscope, there was no oxidized
21	even before induction. But, again, that	21	polypropylene. In that particular spot, the
22	experiment is just they have this one	22	polypropylene had not been oxidized. And
23	it only went out to 30 days, and I just don't	23	then where we see the numbers is where we see
24	think they went far enough to see the stress	24	evidence of oxidation of the polypropylene.
25	cracking.	25	Q What does the C equal sign
	Page 175		Page 177
1	Q I'm looking here, and there is a folder	1	A That's a carbonyl bond. That's also a
2	called TVT six week SEM?	2	reaction product.
3	A Yes.	3	Q Why is there supposedly a carbonyl bond in
4	Q That would be the six-week images?	4	sample two in one week?
5	A Let me open that. Let me pull it up. I	5	A I'm not sure.
6	think that is what it is, but yes, that	6	Q That makes no sense base on the literature
7	would be the six-week images.	7	and data as you understand it, correct?
8	Q Why were SEMs only done on some of the	8	A I wouldn't say it makes no sense. I mean, it
9	samples?	9	could be that small regions of the
10	A We were limited by the number of samples and	10	polypropylene are oxidized before they were
11	just the amount of time to get this work	11	implanted. We have seen that in other
12	done. And so we know that, as I was just	12	exemplars. It is possible that there is
13	explaining, once we reach the induction time,	13	oxidation on the mesh before it's even
14	that we would expect to see these significant	14	implanted
15	physical changes, physical degradation.	15	Q Where would that oxidation come from on the
16	And when the FTIR measurements told us	16	mesh?
17	that it was induced between weeks four and	17	A Thermal processing. When it's extruded and
18	five, we did SEM images at week five, and	18	processed at high temperatures, if those
19	then compared to the pristine sample, because	19	antioxidants get depleted, it's not
20	we were comparing the period in which it's	20	surprising to me that you would see regions
21	become induced. We still have the samples, I	21	we have seen it on exemplars. And I can't
22	believe.	22	say which meshes, but it's possible for the
	And I think we did this really out of	23	mesh to be oxidized during processing.
23	AND LIBER WE WIN THE IVALLY VIII VI		mesh to be obtained duffing processing.
23		24	
23 24 25	time constraints because there was so many samples.	24 25	Q Is it your opinion that this shows the TVT mesh is thermally oxidized?

45 (Pages 174 to 177)

	Page 178		Page 180
1	A That's not what I'm saying. I'm saying that	1	A She said that's what she saw. She trusts her
2	that could be an explanation for why that	2	methods. She stands by her methods. I'm not
3	number is not zero.	3	shocked, because as I said, we have
4	Q Another explanation could be that her test is	4	sufficient oxidation in these meshes. The
5	just wrong, correct?	5	exemplars, you open them out of the box, and
6	MR. KUNTZ: Objection.	6	in some cases, we have seen oxidation. So
7	A I wouldn't say it's just wrong. I would say	7	I'm not shocked by this.
8	that when you look at the XPS as a whole,	8	Q Is it correct that one explanation could be
9	it's consistent with the FTIR data. We see	9	that something was wrong with her equipment
10	regions of oxidation, and those numbers	10	on that date, with the calibration or the
11	generally increase with time. And that point	11	test methods she did on that particular
12	at one week yeah, there could be multiple	12	sample?
13	explanations for that.	13	A It's a possibility, but an unlikely one.
14	BY MR. SNELL:	14	Q Did you go back and look at any documents or
15	Q You would not expect to see a reading at one	15	any log books or anything like that with
16	week for the CO bond, correct?	16	regard to what happened during that testing
17	A No, not if I mean, if it had regions of	17	on week one?
18	oxidation, that could happen. It could have	18	A We looked at Dr. Dunn and I and Dr. Rogers
19	been that in that particular measurement, she	19	reviewed a fair amount of the original data,
20	was looking at a region that hadn't been	20	which she showed us the peaks in the XPS
21	oxidized during processing. That can't be	21	spectra.
22	ruled out.	22	She has an algorithm for separating the
23	Q Well, what are all the possible reasons why	23	peaks, as described in her report, and that's
24	you could find this CO finding in the second	24	what she saw. And, again, this is looking
25	TVT sample at week one, besides there could	25	through a microscope at one small spot on the
	Page 179		Page 181
1	be thermal oxidation that you're saying, I	1	surface, and she saw this region where there
2	guess?	2	was some evidence of oxidation.
3	Could her equipment not be calibrated or	3	Q How small of a spot was that?
4	running properly on that certain day?	4	A I don't know the size of the spot, but I know
5	A I think that is pretty unlikely. I think	5	that she does this through a microscope.
6	that it could be that there was a region in	6	Q Do you have an idea or a range? I mean, are
7	the mesh where the antioxidants had been	7	we talking about couple of microns or 1,000
8	depleted and oxidized very quickly. It could	8	microns?
9	have happened during thermal oxidation. I	9	A It's not you know, 1,000 microns would be
10	mean, those are some examples of what could	10	a millimeter. It's not that big. I don't
11	have happened.	11	know the exact size of the spot.
12	But I don't think one data point that is	12	Q There were no positive findings at week two,
13	somewhat unexpected can be used to support	13	correct?
14	the notion that the method is flawed. You	14	A When you say positive, there was no evidence
15	can't rule out that the polypropylene wasn't	15	none of the spots she looked at at week
16	oxidized. You simply can't really explain	16	two showed evidence of oxidation. That's the
17	that data point. There is several possible	17	way I would describe that.
18	reasons, and none of them is terribly	18	Q And how do you explain that?
19	conclusive.	19	A Well, because she didn't see any evidence of
20	Q Did you ask her why in the world, Doctor, are	20	carbon-oxygen bonds at week two on any of the
21	you showing a positive finding in one week in	21	spots she looked at.
22	the CO bond in the second sample?	22	Q On week three, there were only two findings
23	A We discussed it with her.	23	that were positive, correct?
	Q But what did she say about why that finding	24	A On week three, there were two spots where she
24 25	was there at one week?	25	saw evidence of oxidation.

46 (Pages 178 to 181)

	Page 182		Page 184
1	Q On week three, second sample, it says 0.0088.	1	induction at week five.
2	What does that mean?	2	At week five, we see these remarkable
3	A Let me look at her report in a little more	3	we see two spots, where now we have
4	detail and make sure I answer that correctly.	4	essentially 50 percent of the carbon atoms
5	So table one presents the fraction of	5	which she was looking at that are bound to
6	carbon atoms bonded in the RCOOH and RCO	6	oxygen. We look at these data in week five.
7	configurations. So that would be the	7	The first two samples in the first sample
8	fraction of carbon atoms for that would be 88	8	and the second sample, we see a dramatic
9	percent of the carbon atoms would bond to	9	increase in, so that's what
10	that group is what she is reporting.	10	Q In the third sample, there is no increase,
11	Q At week four, there was only one positive	11	right?
12	finding, correct?	12	A That's a region where well, there is some
13	A Again, there was one spot that showed	13	carbonyl showing up, but that's a region
14	evidence of oxidation.	14	that was less oxidized than the other two.
15	Q Do you know why she didn't have a positive	15	That's the way I would interpret that.
16	finding in the second and third samples, but	16	Q The zero means no oxidation seen, correct?
17	had one the week before supposedly?	17	A Well, I think we have to as Dr. Dunn has
18	A I wouldn't say supposedly. Again, we are	18	testified previously, we need to consider
19	looking at individual spots. And if you look	19	these two peaks together, because we are most
20	at the SEM images, you can see that there are	20	entered in looking at the fraction of carbons
21	regions where there is degradation and then	21	that are bound to oxygen. That tells us
22	regions where there is not. So there are	22	about oxidation. So we do see some carbonyl.
23	regions on the surface of this polypropylene	23	And there is no COOH group in that sample.
24	that are oxidized, and there are regions that	24	And, again, it is because we are looking
25	are not. And this is these are the number	25	at different it depends on the spot that
	Page 183		Page 185
1	of areas that that is what she observed.	1	you are looking at.
2	Q You said you all looked at the raw data where	2	Q The CO, that's the carbon oxygen, the
3	there were these peaks and things like that.	3	carbonyl?
4	Where is that in this production?	4	A The CO is a carbonyl bond.
5	A I don't see that in her report. We have that	5	Q Right.
6	data. I'm not sure where they are.	6	So in the first sample, there was no
7	Q I'm going to request those.	7	positive finding of the CO bond at weeks
8	A Yeah, and that's not going to be a difficult	8	four, five or six, correct?
9	thing to provide.	9	A That's what it says, right.
10	Q Has she done any statistical testing on that	10	Q How do you explain that finding?
11	XPS?	11	A Again, I would look at this as adding
12	A No. And as I mentioned before, XPS is really	12	because these are you know, she is trying
13	a qualitative tool to assess the structure of	13	to separate these two peaks using a
14	the bonds. It's telling us that we see these	14	mathematical algorithm. And, you know, I
15	carbon-oxygen bonds that are indicative of	15	think we have to consider both numbers when
16	degradation. It is confirming the FTIR	16	we talk about whether the surface is oxidized
17	findings. We are relying on the FTIR	17	or not. Both of those types of bonds can
18	findings for a more quantitative analysis	18	occur on the surface. That is the way the
19	where we will run our statistical tests.	19	test works.
20	And it's because with XPS, we are looking	20	Q Even though there were, as she supposedly
21	at different spots, and we can't distinguish	21	records, RCOOH bonding, at weeks four, five
22	whether it's a degraded spot or whether it's	22	and six, there is no CO bonding. That's
23	a non-degraded spot. What the XPS data	23	fair, correct?
24	confirms is that there is regions of	24	A That is what her analysis shows.
25	degradation, and we can even see evidence of	25	Q And there is zeros at even weeks five and

47 (Pages 182 to 185)

	Page 186		Page 188
1	six, correct?	1	Q Have you ever investigated the
2	A Again, it depends on the spot you're looking	2	biocompatibility of porcine slings?
3	at.	3	A What do you mean by biocompatibility? That's
4	Q Is it true or not, though, that there is	4	a pretty controversial word. You mean in an
5	zeros at weeks five and six?	5	ISO context or I'm not sure what you mean.
6	A Yeah, that's what I just said.	6	Q I thought somewhere you talk about
7	Q And these numbers are not consistently	7	biocompatibility.
8	showing oxidation across all samples at the	8	A Where do I talk about biocompatibility? I
9	same time point either; is that correct?	9	want to be very careful with that word
10	A That's correct. And, again, that's because	10	because it has a very evolving meaning.
11	of where you are looking, just like the SEM	11	There is an ISO 10993 biocompatibility test
12	images, not all regions are degraded.	12	that measures certain characteristics of the
13	Q Or it could be because of issues in the test,	13	device. But biocompatibility really can be
14	correct?	14	best understood in the context of the
15	A Unlikely.	15	material and where it's being implanted. I'm
16	Q But that's a possibility?	16	not sure what you're asking about is the
17	A It's always a possibility. I mean, it's a	17	problem.
18	possibility of any test.	18	Q Have you done any analysis on cadaveric
19	Q Have you done any analyses on cadaveric	19	slings for incontinence? Meaning, have you
20	slings?	20	searched the literature to try to understand
21	A No. Cadaveric slings in my understanding	21	whether they degrade, whether they remodel,
22	aren't made of out of polypropylene.	22	anything like that?
23	Q I think I would agree with that.	23	A I have looked at that some, but not my
24	But my question is simple. Have you done	24	understanding is that there is this Burch
25	any testing on cadaveric slings?	25	procedure where they can use autograft, I'm
	Page 187		Page 189
1	A No. Why would I?	1	aware of that, where they harvest autograft,
2	Q I'm just asking.	2	There is the Lynn paper that talks about
3	A Okay.	3	harvesting autograft and then implanting that
4	Q You're reading too much into my question.	4	as a sling. I'm less familiar with the
5	A It's just this kind of came out of no where.	5	allograft and xenograft models. I don't know
6	Q Have you ever done any testing on biologic	6	where you would get allograft for something
7	slings?	7	like this.
8	MR. KUNTZ: Don't do this.	8	But you're saying that there is a pig
9	MR. SNELL: I'm going to come	9	xenograft
10	back to it, I'm sure.	10	Q Sling.
11	BY MR. SNELL:	11	A I'm not so familiar with that.
12	Q Are you aware that biologic slings can	12	Q Okay. Have you have done any research or
13	degrade?	13	seen any literature that specifically looks
14	A Okay. I would not use your terms are a	14	at polypropylene slings and determines that
15	little when you say biologic, are you	15	they did not degrade?
16	talking about like the autograft or the	16	A Again, I would like to be careful about this
17	allograft? What do you mean by biologic?	17	word degrade, so I'm going to answer your
18	Q You know like a pig sling.	18	question as best as I can. I have seen
19 20	A You're supposed to call that a xenograft. I	19 20	papers that report findings that the sling
21	don't know that I would use the word degrade.	20	does not degrade. There is a paper by Professor Drochowski
22	I would prefer to use a word like remodel. It's reabsorbed, you know, so the old tissue	22	There is a paper by Professor Dmochowski at Vanderbilt, he is a co-author on this
23	in the xenograft is absorbed, and then new	23	paper where they looked at but they didn't
24	tissue is deposited by it. That's my	24	use the types of techniques we're talking
25	understanding of what you're saying, I think.	25	about. My understanding of this paper is

48 (Pages 186 to 189)

	Page 190		Page 192
1	degradation was assessed by a pathologist	1	supports these opinions, but it doesn't
2	from an H&E stained section. And it's not	2	change them.
3	clear to me that you would be able to see	3	So if we look at opinion three and we
4	degradation with a method like this unless it	4	talked about this, but if we look at opinion
5	were really bad.	5	three, the antioxidants do not eliminate
6	So I'm aware of those papers, and I have	6	degradation, and they do not guard
7	read them, and I have considered those views.	7	indefinitely against oxidative this is
8	My concern is that they don't always use	8	the testing is relevant to this opinion. But
9	these same techniques.	9	other than that again, it's the same
10	Q What doctor was that? Was that a doctor?	10	opinion. I'm just saying that the testing
11	A Yes. He's a urologist at Vanderbilt.	11	further supports it. It doesn't change the
12	Q Dmochowski?	12	opinion.
13	A Dmochowski. That's who I'm talking about.	13	Q The testing you're referring to is the
14	And I think you know him.	14	testing that we've been looking at?
15	Q Any other papers?	15	A That we've just discussed, yeah.
16	A That's the one that comes to mind. I think	16	Q And that's pertinent to opinion number three
17	there are others too, but that is the one	17	about the antioxidants?
18	that comes to mind. I mean, there is these	18	A I would say it's really pertinent to all
19	Nelson studies and these other papers, but,	19	five, but most specifically of opinion three
20	again, they're not specifically looking	20	I would say. Opinion six, I think, is
21	they may report that there is no degradation,	21	similar. I did talk in Huskey about
22	but when you read the paper, it's well,	22	Ethicon's internal documents I'm referring
23	in this case, they do patient surveys.	23	to oxidative degradation.
24	So how are you going to know that the	24	Q Which document are you talking about there?
25	mesh degraded if you're just talking to	25	A There is the Guidon study, the eight-year
	Page 191		Page 193
1	someone in a survey. So I'm aware that those	1	explanted suture study. There is some other
2	papers are out there, and I have a read a	2	the dog study even shows evidence of
3	number of them.	3	degradation. Those are the two that come to
4	MR. SNELL: We are going to mark	4	mind.
5	your summary of opinions as the next exhibit.	5	There is some comments in those reports
6	(Deposition Exhibit No. 4 was	6	about scraping off material that appeared to
7	marked for identification.)	7	be degraded polypropylene on the basis of its
8	BY MR. SNELL:	8	melting point and appearance, and
9	Q So as we go through your opinions and just	9	environmental stress cracking in the sutures.
10	to perhaps save us a little time, these are	10	All of that was discussed in Huskey.
11	the similar or the same opinions that you had	11	Q In the Guidon eight-year explant suture study
12	at the Huskey case, correct?	12	that you referenced, when did those findings
13	A Yes, most of them are. If it would help, I	13	of dyspareunia show?
14	can distinguish which opinions have been	14	A When did those findings of dyspareunia see
15	modified or are different since Huskey.	15	that. You're being cheeky now.
16	Q Yes, that would be great.	16	Q Yeah.
17	Let me ask you to look at the exhibit we	17	In the Guidon finger explant suture,
18	marked for your summary of opinions in	18	that's the vascular graft?
19	Mrs. Perry's case, and tell us if the	19	A That's right.
20	opinions have been changed or added or	20	Q All right. At what point did the positive
21	modified as compared to your Huskey opinion.	21	findings that you relied on show up on that
22	A So I believe opinions one, and two, and	22	study?
	three, four, five, those five opinions are	23	A So it was the eight-year time point where the
23			
	very similar to Huskey. What I would say is new is the testing that we did further	24 25	surface cracking became I think there was some cracking observed at earlier time

49 (Pages 190 to 193)

	Page 194		Page 196
1	points, but in eight years, I remember it	1	point. Now, I'm looking at the seven year
2	being very severe.	2	time point. And the conclusions I am reading
3	Q And the dog study, at what point in time did	3	here, the seven-year in vivo results
4	any of those findings become significant?	4	generally substantiated the five-year
5		5	
6	A I would have to look at the documents again,	6	findings, degradation in Prolene is still
7	but my latest review of them, it was what	7	increasing.
	I remember is the conclusion from the study		So the way I interpret this is from year
8	is that the cracking became worse with time,	8	five to year seven, the degradation is
9	up to seven years. Again, that was all	9	progressing, but I don't see any SEM images
10	discussed in Huskey.	10	here.
11	Q I didn't see that. I don't know if you	11	Q Do you know from that study when the cracking
12	focused on the timing.	12	first appeared, besides in five years?
13	A Okay. Well, I just read this last night when	13	A A few time points I have is five years and
14	I was preparing, and I remember some	14	seven years is what's shown in this study.
15	statements saying that the cracking appeared	15	And then the fact that it got worse from year
16	to get worse. We can pull it up if you want	16	five to year seven, and that's what is
17	to talk about it.	17	reported in this study. And that's what I am
18	Q Yes, let's just pull it up. I just want to	18	relying on for this opinion.
19	understand what you're talking about.	19	Q That study doesn't establish that the
20	It would be under reliance documents?	20	cracking was there at, say, three years?
21	A I believe it would be.	21	A It doesn't establish it was there at three
22	Q Do you remember how you had it labeled?	22	years because there was no three-year time
23	MR. KUNTZ: Do you want to ask	23	point.
24	some questions about it?	24	Q All you know is that at five years, two out
25	MR. SNELL: Yes, just that one	25	of the overall sample had some cracking?
	Page 195		Page 197
1	question about the time point.	1	A That's right.
2	MR. KUNTZ: You can use my copy,	2	Q So you were looking at your list of opinions,
3	but I don't want it marked as an exhibit. It	3	and you had talked about number six. And
4	has highlights on it. I mean, just to speed	4	number seven?
5	things up.	5	A So number seven, Ethicon ignored the warning
6	MR. SNELL: That's fine.	6	contained in the MSDS for the polypropylene
7	(Off-the-record discussion.)	7	use in its products. It says the strong
8	BY MR. SNELL:	8	oxidizing agents, like peroxides, are
9	Q Okay. Go ahead.	9	incompatible with the polypropylene to the
10	A I'm just going to give you some points here.	10	detriment of patients implanted with the
11			• •
	So there is my understanding is that this	11	mesh. So the MSDS warns that polypropylene
12	dog study was designed to be a ten-year	12	is sensitive to oxidation.
13	study. There was a five-year report that was	13	Again, our testing plays into this
14	issued. In five years, two out of the seven	14	because our testing has shown that even with
15	Prolene explants revealed cracking in five	15	the antioxidants, it can oxidize. They don't
16	years. And then there is some SEM images	16	protect it forever, as I've wrote in opinion
17	here that show those explants, and I can see	17	three. And this is a detriment to patients
18	the cracking that they're referring to in two	18	implanted with the mesh for two reasons.
19	of those explants.	19	One is, we've seen that oxidation
20	I would say that at least in the image I	20	degradation can lead to embrittlement, pain,
21	have it's difficult to tell, but it looks	21	and complications, as I have testified, with
22	like there is a third one that might be	22	Costello and Clave and Huskey in previous
23	showing some evidence as well. This is what	23	testimony, and it increases the risk. It's
24	I can see in these micrographs that are not	24	unpredictable, so it increases the risk to
25	terribly clear. That was the five-year time	25	the patients. It's a risk that they have to

50 (Pages 194 to 197)

live with for their entire lives because the device is there. And as long as it's there, it's going to be this reaction is ongoing. That's opinion five. And it's important that the antioxidants don't protect it forever. Q That's basically the same as what you expressed in Huskey? A I believe it is. I just wanted to qualify that I do believe that the testing data has some impact on that opinion, and we've been discussing that. But it's a similar opinion to that held in Huskey. A Number eight, I think, is also similar to Huskey. I provide evidence of oxidation and degradati and conclude that that contributed to the embrittlement of the mesh. That could be done. I did not do that in this case. I didn't have the materials, but I don't want to I would say from I don't maybe to give you a better answer, I am not reviewing medical records and 9 Q You're not doing a differential diagnoses an drawing causal relationship inferences? A Not in this case, no. Q Nor in general, correct? A I have testified that again, I saw evidence of myeloperoxidase, which was evidenced to me that these oxidative processes are ongoing. That would lead to	
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15 A Number eight, I think, is also similar to 15 evidenced to me that these oxidative	- Ili
\mathcal{S}	
17 Q In Huskey, as I recall it I mean, the 17 changes in the polypropylene. So in terms of	,
primary studies and documents that you 18 you had a question?	
referred to and relied upon were the dog 19 Q The myeloperoxidase is not something you	have
20 study, the vascular suture graft study, 20 done on an Ethicon mesh?	nave
21 Clave, Costello? 21 A That's correct.	
22 A Yes. 22 Q It's not something you have done on an	
23 Q The other one you mentioned today, Liebert, 23 explant from an Ethicon patient to your	
24 is that another one that is important to your 24 knowledge?	
25 opinions? 25 A To my knowledge. It may be in	
	201
1 A Yes, all of those studies that we've 2 discussed. 1 Dr. Iakovlev's, but I don't know. 2 Q And you understand that doctors are the on	, g
	×S
3 Q Okay. 3 who actually do differential diagnoses and draw conclusions about what complications	
5 object. We have provided everything to you 5 patients have?	
6 he has relied on. It's not a memory test to 6 A Could you explain differential diagnosis,	
7 point out every single document, but I think 7 please?	
8 I understand your question. 8 Q Let me ask you, do you know what a	
9 A I testified that on those at Huskey, and my 9 differential diagnosis is?	
opinion has not changed in that regard. 10 A Not precisely, I don't thinK. So I suppose 1	
11 BY MR. SNELL: 11 wouldn't do that. I mean, it sounds like a	
12 Q And so I'm not going to recover those things 12 medical term to me.	
with you. 13 Q Opinion number nine, explain that opinion	_
13 With you. 14 A That would be great. 15 Q Opinion indinder line, explain that opinion and the companion of the companion	
15 Q You're not offering any medical or clinical 15 A So after reviewing all of the Ethicon	
opinions with regard to Mrs. Perry at all; is 16 documents and some published papers, my	
that correct? 17 documents and some published papers, my	is
18 A That's correct. 18 stiffer. There are several e-mails from	10
19 Q That would be totally outside your expertise, 19 inventors of the mesh, such as Dr. Della	
20 correct? 19 Wellon, that observed this	
21 A Medical and 21 increase in stiffness, complained about an	
22 Q Clinical? 22 increase in complications, asserted that this	
23 A Medical and clinical? Just for the record, I 23 mesh was different, and you could not rely	
24 would not say it would be outside my 24 upon TVT machine-cut mesh data to suppor	the
25 expertise to test the explanted mesh and 25 notion that TVT Abbrevo is the same.	

51 (Pages 198 to 201)

	Page 202		Page 204
1	I reviewed mechanical testing done by	1	the decision-making process, not I did not
2	Ethicon, and an effort by Dr. Kammerer, I	2	test these meshes mechanically. I'm making
3		3	
	believe, who is a fellow at Ethicon, who		this opinion on the basis of Ethicon
4	basically replotted some of those data and	4	documents where they chose they
5	argued from Lynn that the mesh is subject to	5	deliberately selected different ranges over
6	the very small forces in this environment.	6	which to view the mechanical data. That's
7	And when you compare over that very small	7	what I'm questioning.
8	force range, he reported that the elongation,	8	Q Well, I'm going to get to that. My focus is
9	the mechanical properties are the same.	9	on the e-mails.
10	I do not think this is a good way to	10	Basically, what you did is you looked at
11	approach the problem. I think you would have	11	some e-mails that some people wrote, and you
12	to consider as in the paper by Dietz, where	12	adopted what they said, correct?
13	he went out to 80 percent, something okay.	13	A Well, what do you mean I adopted what they
14	So with the original Ethicon testing, they	14	said?
15	went to 14 or 15-percent elongation. The	15	Q Did you assume what was written on the paper
16	Dietz paper went out to maybe 80-percent	16	was accurate or true?
17	elongation. And at those higher elongations,	17	MR. KUNTZ: I'm just going to
18	there are significant differences, stiffness	18	object.
19	of TVT machine-cut and TVT laser-cut.	19	A I'm still not getting it. I mean, there was
20	Dr. Kammerer only plotted the data over a	20	statements by these surgeons that said it's
21	range of up to about a 4-percent strain	21	not the same.
22	elongation, and that was just a very limited	22	BY MR. SNELL:
23	range. He concluded that they were similar,	23	Q Okay. This is what I am just asking maybe
24	but I questioned the physiological relevance	24	I'm making it too complex.
25	of his approach in asserting that Lynn could	25	A Okay. I'm just not getting something.
	Page 203		Page 205
1	be used to support that assumption. That's	1	Q You saw some statements in an e-mail?
2	my opinion.	2	A Yes.
3	So the mesh, I believe, is stiffer. And	3	Q And you read them and what they meant to you,
4	the decision was made to use the TVT	4	right?
5	machine-cut data that is for the laser-cut	5	A Yeah. It seemed like a straight forward
6	product even though it was different. That's	6	statement. And I read it and that's what it
7	my opinion on number nine.	7	said, so I just
8	Q So you looked at the e-mails where	8	
		9	Q You didn't apply any further analysis to this
9 10	Dr. Della Valle or others may have written in comments about the mesh being stiffer,	10	statement? A What further analysis would I have applied?
		1 T U	
1 1			
11	correct?	11	It is just what it said. There were multiple
12	correct? A I reviewed those e-mails, yeah.	11 12	It is just what it said. There were multiple e-mails and there was an e-mail chain. I
12 13	correct? A I reviewed those e-mails, yeah. Q So you read those the e-mails, and you	11 12 13	It is just what it said. There were multiple e-mails and there was an e-mail chain. I read the question, and I read the response,
12 13 14	correct? A I reviewed those e-mails, yeah. Q So you read those the e-mails, and you basically took as what they said to be as	11 12 13 14	It is just what it said. There were multiple e-mails and there was an e-mail chain. I read the question, and I read the response, and I I mean, I did my best to review it,
12 13 14 15	correct? A I reviewed those e-mails, yeah. Q So you read those the e-mails, and you basically took as what they said to be as true, right?	11 12 13 14 15	It is just what it said. There were multiple e-mails and there was an e-mail chain. I read the question, and I read the response, and I I mean, I did my best to review it, but some of these comments were rather blunt
12 13 14 15 16	correct? A I reviewed those e-mails, yeah. Q So you read those the e-mails, and you basically took as what they said to be as true, right? A I read as much as I could read. I read a lot	11 12 13 14 15 16	It is just what it said. There were multiple e-mails and there was an e-mail chain. I read the question, and I read the response, and I I mean, I did my best to review it, but some of these comments were rather blunt and direct, so it was
12 13 14 15 16 17	correct? A I reviewed those e-mails, yeah. Q So you read those the e-mails, and you basically took as what they said to be as true, right? A I read as much as I could read. I read a lot of documents.	11 12 13 14 15 16 17	It is just what it said. There were multiple e-mails and there was an e-mail chain. I read the question, and I read the response, and I I mean, I did my best to review it, but some of these comments were rather blunt and direct, so it was Q So you interpreted the statements without
12 13 14 15 16 17	correct? A I reviewed those e-mails, yeah. Q So you read those the e-mails, and you basically took as what they said to be as true, right? A I read as much as I could read. I read a lot of documents. Q How about this, what independent testing did	11 12 13 14 15 16 17 18	It is just what it said. There were multiple e-mails and there was an e-mail chain. I read the question, and I read the response, and I I mean, I did my best to review it, but some of these comments were rather blunt and direct, so it was Q So you interpreted the statements without doing any testing of their veracity or of
12 13 14 15 16 17 18	correct? A I reviewed those e-mails, yeah. Q So you read those the e-mails, and you basically took as what they said to be as true, right? A I read as much as I could read. I read a lot of documents. Q How about this, what independent testing did you do, if any, to confirm or not confirm	11 12 13 14 15 16 17 18	It is just what it said. There were multiple e-mails and there was an e-mail chain. I read the question, and I read the response, and I I mean, I did my best to review it, but some of these comments were rather blunt and direct, so it was Q So you interpreted the statements without doing any testing of their veracity or of the points?
12 13 14 15 16 17 18 19 20	correct? A I reviewed those e-mails, yeah. Q So you read those the e-mails, and you basically took as what they said to be as true, right? A I read as much as I could read. I read a lot of documents. Q How about this, what independent testing did you do, if any, to confirm or not confirm the supposed higher level of stiffness of	11 12 13 14 15 16 17 18 19 20	It is just what it said. There were multiple e-mails and there was an e-mail chain. I read the question, and I read the response, and I I mean, I did my best to review it, but some of these comments were rather blunt and direct, so it was Q So you interpreted the statements without doing any testing of their veracity or of the points? A I don't know how to test their veracity. It
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12 13 14 15 16 17 18 19 20 21 22	correct? A I reviewed those e-mails, yeah. Q So you read those the e-mails, and you basically took as what they said to be as true, right? A I read as much as I could read. I read a lot of documents. Q How about this, what independent testing did you do, if any, to confirm or not confirm the supposed higher level of stiffness of the mesh? A Well, honestly I felt like I didn't need to	11 12 13 14 15 16 17 18 19 20 21 22	It is just what it said. There were multiple e-mails and there was an e-mail chain. I read the question, and I read the response, and I I mean, I did my best to review it, but some of these comments were rather blunt and direct, so it was Q So you interpreted the statements without doing any testing of their veracity or of the points? A I don't know how to test their veracity. It just I mean, there were multiple statements and there were multiple e-mails

52 (Pages 202 to 205)

	Page 206		Page 208
1	be many documents posing the question is TVT	1	A That's the difference to my understanding,
2	machine-cut the same as TVT laser-cut Abbrevo	2	that's the only difference in how they are
3	laser-cut versus the machine-cut.	3	manufactured, but that could introduce
4	There were numerous opinions and	4	differences well, okay.
5	documents going back and forth. Many were	5	Q But they are the same in that respect,
6	questioning this decision. Others were	6	correct?
7	promoting it. There was it looked like a	7	A The same in what respect?
8	fair amount of descension until Dr. Kammerer	8	Q That they are the same up until the point
9	did his analysis, and then what appeared to	9	when they decide to cut the edges of the mesh
10	me is that the decision was taken that these	10	either mechanically or they do it with
11	products are the same.	11	laser, correct?
12	So I read a lot of documents to form	12	A I understand, yeah.
13	this. I mean, if there is another one you	13	Q Is that correct?
14	would like me to read, I would be happy to	14	A I believe so. I mean, I don't have the
15	read it. That's why I'm here. But this is	15	details of how these are
16	what I read, and this is what I saw, and this	16	Q So if we have two pieces of mesh, this is
17	is the opinion I came to.	17	mechanical, this is laser, is there any
18	Q I mean, these were basically e-mails written	18	difference in the mesh that is running down
19	by other people who wrote into the company.	19	the middle?
20	And that's what you looked at, correct?	20	A I don't know. That has not been tested. All
21	A Yes, but some were internally e-mails between	21	I can say is that they are cut differently.
22	conversations between Ethicon employees	22	What affect that has on the mesh in the
23	and Europe and North America and	23	middle, I don't know that that's been tested.
24	Q Fair enough.	24	Q They are knitted the same, right?
25	These are people writing e-mails to other	25	A Yeah, but that cutting operation could change
23	Page 207	23	Page 209
_			
1	people, correct?	1	something. I just don't know and it's not
2	A Yes.	2	been looked at.
3	Q The laser-cut and the mechanical cut mesh,	3	Q Well, Dr. Kammerer looked at it, right?
4	they are the same mesh, correct?	4	A No. Dr. Kammerer, I don't believe he
5	MR. KUNTZ: Objection.	5	actually did any testing. I believe Dr.
6	A I would say they are cut from the same	6	Kammerer took data from previous experiments
7	Prolene mesh, but I would not say that they	7	and replotted them over a different range of
8	are the same mesh. One has cut edges with a	8	elongation. That's what I believe he did
9	machine, the other has a cut with a laser.	9	from the documents I saw.
10	That's not the same to me. But if you want	10	I didn't see all I saw in his report
11	to say they're prepared from the same source	11	was that he noted that he was using data from
12	mesh, I believe that's correct.	12	other reports. I didn't see like he actually
13	BY MR. SNELL:	13	did do measurements. That was my
14	Q Both of the meshes are made of the same	14	understanding.
15	Prolene polypropylene, correct?	15	Q The elongation of the mesh, the
16	A That's my understanding.	16	mechanically-cut and the laser-cut, were the
17	Q And it's the same mesh that goes through all	17	same at out to I believe it was 5 percent.
18	of the same extrusion and manufacturing	18	Do you have the document?
19	processes up until the point when it's cut to	19	A It would help if we had the document. I was
20	your understanding, correct?	20	going on my memory. I believe it was 4
21	A That's my understanding.	21	percent maybe. It was not very many. I
22	Q Right.	22	believe it was 4 percent. It would help if
23	The only difference is the edges of the	23	we had it. I don't know if it's on the disk
24	strip of tape, one is cut mechanically and	24	or, I mean, how easy it would be to find.
25	one is cut with a laser, correct?	25	Q It will be on there. I'm sure if you'd look

53 (Pages 206 to 209)

	Page 210		Page 212
1	at it, it's on there.	1	Does that make sense?
2	MR. KUNTZ: What are you looking	2	Q This is the sling under the urethra, correct
3	for again?	3	A Yeah.
4	MR. SNELL: Kammerer's paper,	4	Q Do you know the size of the urethra?
5	the elongation testing.	5	A Probably pretty small.
6	MR. KUNTZ: Which one?	6	Q So that low number, that small number do
7	MR. SNELL: The analysis he did	7	you understand that? Do you know whether
8	on elongation of the laser-cut versus the	8	that is consistent or inconsistent with basic
9	mechanical-cut. I want him to be able to	9	anatomy and physiology of the urethra, in the
10	look at it.	10	support structures lying underneath the
11	(Off-the-record discussion.)	11	urethra?
12	BY MR. SNELL:	12	A It just seems to me that the sling in that
13	Q Have you ever tested the forces in the	13	study is different from the slings that are
14	pelvis?	14	being used as the TVT. It's placed
15	A No, I have not.	15	differently. I just don't know that you can
16	Q What is your basis for saying that the	16	make that same extrapolation, that the force
17	reliance on the Lynn period paper is wrong?	17	on that autograft sling when somebody coughs
18	A Okay. So there is another okay. There is	18	is the same. It just seems
19	another e-mail by Dr. Kammerer, where he	19	Q Do you know that you can't? I mean, have you
20	comments that the elongation on the mesh	20	done any testing or done any research that
21	could be as high as 50 percent when it is	21	ever shows that one cannot do that?
22	implanted. And, obviously, if the mesh is	22	MR. KUNTZ: Objection. From
23	elongated when it's implanted, that's going	23	what he has already said? From what Kammerer
24	to move you down the force-distance curve.	24	has already said? I just want to make sure
25	And the other point about Lynn is that	25	we're clear.
25	· · · · · · · · · · · · · · · · · · ·	23	Page 213
	Page 211		
1	what Lynn was really measuring was a	1	MR. SNELL: No, I'm asking him.
2	differential force. So Lynn was measuring	2	He says he doesn't know. Well, what I'm
3	so the patients were grafted with this what	3	asking you is
4	looked like the autograft fascia sling, and	4	MR. KUNTZ: He just referred to
5	he was measuring the force when they cough	5	Ethicon's own document, where Gene Kammerer
6	with a full or empty bladder. That is a	6	said it was different. Besides that?
7	differential force. You don't know what the	7	MR. SNELL: No, he didn't.
8	initial force or tension of the elongation of	8	MR. KUNTZ: Yeah, he did. He
9	that sling was.	9	said his e-mail yes, he said exactly that.
10	And the differential forces that he was	10	
		l .	And now you're trying to say that he didn't.
11	measuring were so small. They are something	11	A I'm saying that Dr. Kammerer said that when
12	measuring were so small. They are something in the range of .1 to .2 pounds. I mean,	12	A I'm saying that Dr. Kammerer said that when you implant a sling, it can elongate as much
12 13	measuring were so small. They are something in the range of .1 to .2 pounds. I mean, that's like taking the meat patty from a	12 13	A I'm saying that Dr. Kammerer said that when you implant a sling, it can elongate as much as 50 percent. And 4 percent I mean, I've
12 13 14	measuring were so small. They are something in the range of .1 to .2 pounds. I mean, that's like taking the meat patty from a junior cheeseburger and hanging it on I	12 13 14	A I'm saying that Dr. Kammerer said that when you implant a sling, it can elongate as much as 50 percent. And 4 percent I mean, I've seen these slings. For 4 percent, that's
12 13 14 15	measuring were so small. They are something in the range of .1 to .2 pounds. I mean, that's like taking the meat patty from a junior cheeseburger and hanging it on I mean, we are talking forces that are really	12 13 14 15	A I'm saying that Dr. Kammerer said that when you implant a sling, it can elongate as much as 50 percent. And 4 percent I mean, I've seen these slings. For 4 percent, that's like 4-percent elongation is like folding
12 13 14 15 16	measuring were so small. They are something in the range of .1 to .2 pounds. I mean, that's like taking the meat patty from a junior cheeseburger and hanging it on I mean, we are talking forces that are really small. And that's a differential force on a	12 13 14 15 16	A I'm saying that Dr. Kammerer said that when you implant a sling, it can elongate as much as 50 percent. And 4 percent I mean, I've seen these slings. For 4 percent, that's
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12 13 14 15 16 17 18 19 20	measuring were so small. They are something in the range of .1 to .2 pounds. I mean, that's like taking the meat patty from a junior cheeseburger and hanging it on I mean, we are talking forces that are really small. And that's a differential force on a sling when somebody coughs. It just doesn't seem very plausible to me. It's a very small force. If the sling is elongated up to 50 percent, when it's	12 13 14 15 16 17 18 19 20	A I'm saying that Dr. Kammerer said that when you implant a sling, it can elongate as much as 50 percent. And 4 percent I mean, I've seen these slings. For 4 percent, that's like 4-percent elongation is like folding it out of the box. I mean, it's such a small amount. When you install it, it could be 40 or 50-percent strain, and that moves you much further down that stress-strain curve where
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12 13 14 15 16 17 18 19 20 21 22	measuring were so small. They are something in the range of .1 to .2 pounds. I mean, that's like taking the meat patty from a junior cheeseburger and hanging it on I mean, we are talking forces that are really small. And that's a differential force on a sling when somebody coughs. It just doesn't seem very plausible to me. It's a very small force. If the sling is elongated up to 50 percent, when it's then it's got some strain, and you don't know what that is. But that's going to make the	12 13 14 15 16 17 18 19 20 21 22	A I'm saying that Dr. Kammerer said that when you implant a sling, it can elongate as much as 50 percent. And 4 percent I mean, I've seen these slings. For 4 percent, that's like 4-percent elongation is like folding it out of the box. I mean, it's such a small amount. When you install it, it could be 40 or 50-percent strain, and that moves you much further down that stress-strain curve where these materials become very, very different. That is Dr. Kammerer's email. And then he

54 (Pages 210 to 213)

	Page 214		Page 216
1	that's what it was, because he doesn't know	1	That's what he says in the report.
2	the initial force on that sling.	2	I mean, I can read from it if you want
3	He just knows that when somebody coughs	3	to, but that's to me what he said. He used
4	and exerts an additional force, that force	4	Lynn to justify that half a newton of force.
5	was in the range of half a newton.	5	Q Have you have read Dr. Kammerer's deposition?
6	BY MR. SNELL:	6	A I can't remember. I don't know. I don't
7	Q How do you know what Dr. Kammerer knows?	7	remember anything specific from his
8	A Well, that's what he wrote.	8	deposition.
9	Q Well, you just testified that he didn't know	9	Well, I would be interested to
10		10	Q You would be interested to what?
11	something. How do you know that?	11	
12	A What did I say? I don't know what I said he	12	A No, I'm just
	didn't know. I don't know. He said that		MR. KUNTZ: I would be
13	when you implant the sling, it can extend,	13	interested why we got that e-mail after his
14	it can elongate as much as 50 percent. Well,	14	depo, but we can take that up with somebody
15	that's a lot more than 4 percent.	15	else.
16	Q Do you know what that was in the context of	16	BY MR. SNELL:
17	and what type of testing that was in the	17	Q Item number ten, I think this was something
18	context of?	18	that was in Huskey, but you tell me if I'm
19	A In my understanding of reading that e-mail,	19	wrong.
20	that was in the context of the procedure, of	20	A There is an element to that. What's new here
21	implanting the sling.	21	would be referring to this laser-cut versus
22	Q The 50-percent elongation testing you've seen	22	machine-cut. I don't believe to my
23	done, they didn't even have the sheath on the	23	knowledge, the studies that were done were
24	mesh; is that correct? Do you know what I'm	24	this mechanical testing that I was referring
25	talking about? Have you seen 50-percent	25	to. There was a 14-day rabbit study where
	Page 215		Page 217
1	elongation testing?	1	they were measuring the infiltration, and
2	A I'm not talking about testing. In	2	they were measuring pull-out strength, but it
3	Dr. Kammerer's e-mail, he talked about with	3	was a very short time point, only 14 days.
4	the meshes and the procedures he's observed,	4	And then there were e-mails from some of
5	the mesh can elongate up to 50 percent. That	5	these clinicians saying that we can't you
6	was, I think, the language that he used. So	6	just can't use TVT machine-cut clinical data
7	that tells me when it is being implanted,	7	to support TVT machine-cut, the notion that
8	it's elongating. It's no longer it's not	8	the TVT laser-cut would perform the same,
9	4 percent. I mean, he is saying it could be	9	because the meshes are different. And I
10	up to 50 percent. That is a much bigger	10	don't think they did enough testing to
11	number than meaning 4. So I'm questioning	11	establish whether they were different or not.
12		12	
	how he got this he basically took this		I would have liked to have seen more testing to establish that fact.
13	number of 4-percent strain, which is very	13	
14	low, so he could argue that that's what it	14	Q What testing was done?
15	looks like, that he could argue that over	15	A What testing was done?
16	that very small strain that these meshes are,	16	Q That's you're aware of.
17	in fact, the same.	17	Well, let me back up.
18	Q That is your inference of what was going	18	A Okay.
19	through his head?	19	Q Did you do a PubMed or any other kind of
20	A That's what he said in this document. He	20	search to see what clinical literature there
21	puts that number for Lynn out, and then he	21	was on the Abbrevo or laser-cut and
22	goes to that stress strain curve, and he	22	mechanical-cut meshes?
23	plotted the data over that range that he felt	23	A I think there is some study on TVTS, which is
24	was physiologically relevant on the basis of	24	a but that product is off the market now.
25	the findings from Lynn. That's what he did.	25	I was relying heavily on these Ethicon

55 (Pages 214 to 217)

	Page 218		Page 220
1	documents, what they did, and the conclusions	1	offer an opinion that a 510(k) should have
2	that they drew from the testing that they	2	been filed for laser-cut? Because if you
3	did. And I just thought that it wasn't it	3	are, I want you to tell me
4	wasn't enough. It wasn't convincing from the	4	A I know what you want me to tell you.
5	way that the whole Kammerer conclusions were	5	Q the regulations, and I want you to tell me
6	drawn to a 14-day rabbit test. There should	6	exactly what documents they should have
7	have been more preclinical testing.	7	looked at. I want you to basically sit there
8	I mean, why did they not file a new	8	and be a regulatory expert.
9	510(k)? That could have been a relatively	9	A I get it.
10	straight forward thing to do.	10	MR. KUNTZ: He will not be
11	But to my knowledge, they didn't even	11	giving that opinion.
12	file a new 510(k) for the laser-cut mesh.	12	BY MR. SNELL:
13	They just said it's the same without really	13	Q Can you just tell me you're not going to give
14	enough testing to reach that conclusion.	14	that opinion and then I can move on?
15	There was a process change that was just made	15	A I'm upset about what was done. But so we can
16	and never really validated. That's what that	16	move on, I'm not going to give that opinion
17	opinion was saying.	17	as a regulatory expert. There were just
18	Q The e-mails from the clinicians, that's the	18	things that concerned me, but I'm not going
19	same ones we talked with about with regard to	19	okay. I will retract that.
20	opinion number nine?	20	MR. SNELL: Jeff, he is not
21	A Yeah.	21	going to get up at trial
22	Q And the 14-day rabbit study?	22	MR. KUNTZ: He's not going to
23	A That's what I remember. I think there was a	23	give a 510(k).
24	14-day rabbit study.	24	A I'm not giving a 510(k) opinion.
25	Q Do you know if that is the type of study that	25	MR. KUNTZ: That's what you want
	Page 219		Page 221
1	is normally done in the industry to assess	1	to know.
2	pull-out force?	2	A I'm not giving a 510k opinion.
3	A That was my understanding.	3	BY MR. SNELL:
4	Q Have you have ever conducted that type of	4	Q Because that's a whole other issue.
5	study?	5	A I know.
6	A I have not. And I think that answers one	6	Q There is nothing in your disclosures that say
7	question about pull-out force, but I don't	7	he is a regulatory expert and he's talking
8	know that that addresses his question of	8	510(k)'s.
9			310(k) s.
	differences in stiffness between the mesh.	9	A I just have enough knowledge of this that I
10	differences in stiffness between the mesh. And then these clinicians are saying that	9 10	A I just have enough knowledge of this that I saw things that disturbed me, but I'm not
11	And then these clinicians are saying that they are seeing more complications. So there		A I just have enough knowledge of this that I
11 12	And then these clinicians are saying that	10	A I just have enough knowledge of this that I saw things that disturbed me, but I'm not
11 12 13	And then these clinicians are saying that they are seeing more complications. So there were clinical warnings coming back that this that something seems different here.	10 11	A I just have enough knowledge of this that I saw things that disturbed me, but I'm not going to give that opinion as a 510(k) expert. I will stick to what I told you. I will reign myself in. You are provoking me a
11 12 13 14	And then these clinicians are saying that they are seeing more complications. So there were clinical warnings coming back that this that something seems different here. Q Are you a regulatory expert, such that you	10 11 12	A I just have enough knowledge of this that I saw things that disturbed me, but I'm not going to give that opinion as a 510(k) expert. I will stick to what I told you. I will reign myself in. You are provoking me a little bit. I'm not frustrated. I'm just
11 12 13 14 15	And then these clinicians are saying that they are seeing more complications. So there were clinical warnings coming back that this that something seems different here. Q Are you a regulatory expert, such that you can cite to any regulations right now that	10 11 12 13 14 15	A I just have enough knowledge of this that I saw things that disturbed me, but I'm not going to give that opinion as a 510(k) expert. I will stick to what I told you. I will reign myself in. You are provoking me a
11 12 13 14 15	And then these clinicians are saying that they are seeing more complications. So there were clinical warnings coming back that this that something seems different here. Q Are you a regulatory expert, such that you can cite to any regulations right now that say that Ethicon should have filed a 510(k)	10 11 12 13 14 15 16	A I just have enough knowledge of this that I saw things that disturbed me, but I'm not going to give that opinion as a 510(k) expert. I will stick to what I told you. I will reign myself in. You are provoking me a little bit. I'm not frustrated. I'm just Q You know what they say, some knowledge is dangerous.
11 12 13 14 15 16 17	And then these clinicians are saying that they are seeing more complications. So there were clinical warnings coming back that this that something seems different here. Q Are you a regulatory expert, such that you can cite to any regulations right now that say that Ethicon should have filed a 510(k) specific to laser-cut mesh?	10 11 12 13 14 15 16 17	A I just have enough knowledge of this that I saw things that disturbed me, but I'm not going to give that opinion as a 510(k) expert. I will stick to what I told you. I will reign myself in. You are provoking me a little bit. I'm not frustrated. I'm just Q You know what they say, some knowledge is dangerous. A I'm going to stay within the scope of my
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56 (Pages 218 to 221)

implantation test than just 14 days. I think if there were differences in siffness, you a might have seen it in 90 days, but even so might have seen it in 90 days, but even longer periods would have been ested in preclinical models could have been ested in preclinical models more relevant to the vaginal wall. So there is something new in my reliance materials. There is an abstract by Deprest, 50 D-E-P.R.F.ST. That was published in 2013. It's in the reliance materials, where they had a large animal model where they compared mesh in the abdominal wall to mesh in the aginal wall, and they saw eightfold more done by Ethica to a seases these differences. I think these studies could have been done by Ethica to a seases these differences. I think they could have interpreted their own emchanical data more conservatively. We already discussed that, so I don't want to bring that up again, but those are the 21 studies. But more preclinical studies and a mechanical data is what I would say. 23 mechanical data is what I would say. 24 Q. Your en ot saying hat Gene Kammerer, who has got 40 years of experience, is incompetent. 25 you've got one, but I haven't seen a document that -1 was a sheep. It is an abstract, I don't like the way that the handled the mechanical data to say that everything was the same. I think that way incorpered. 26 you know what he did was incorped. 27 you was not saying he is incompetent. I don't like the way that don't like. I don't like the way the don't like. I don't like the way the approached that problem. I shouldn't say only the service of mesh, but I can't remember the details from that. It's in the abstract. I don't but come that a laser-cut mesh has ever been subjected to testing in that the vaginal wall. 31 you know whothey implanted it in the vaginal wall. 42 you have not conducted any independent testing or analyses that would show what he did was incorpered. 44 years of experience, is incompetent. 45 you've got one, but I haven't seen that. 15 you've got one, but I haven't seen that. 15		Page 222		Page 224
2 if there were differences in sifffness, you 3 might have seen it in 90 days, but even 4 longer periods would have been —this mesh 5 could have been tested in preclinical models 6 more relevant to the vaginal wall. So there 7 is something new in my reliance materials. 8 There is an abstract by Deprest, 10 It's in the reliance materials, where they 11 had a large animal model where they compared 12 mesh in the abdominal wall to mesh in the 13 vaginal wall, and they saw eightfold more 14 contraction in the vaginal wall. 15 So I think these studies could have been 16 done by Efficion to assess these differences. 16 already discussed that, so I don't want to 17 bring that up again, but those are the 18 own mechanical data more conservatively. We 19 already discussed that, so I don't want to 20 bring that up again, but those are the 21 studies. But more preclinical studies and a 22 more thoughtful evaluation of their own 23 mechanical data is what I would say. 24 Q You're not saying that Gene Kammerer, who has 25 you just disagree with —let me just finish. 2 you just disagree with what he did was 24 A He might be too confident. What he did was 25 —I don't like it. I don't like the way 26 that he handled the mechanical data to say 27 that everything was the same. I think that 28 was a lawed approach. Than rots atying he is 29 incompetent. I don't like the way the 29 don't like. I disagree with it. 20 Q But you have not conducted any independent testing or analyses that would show what he 29 did was incorrect? 3 A I was a sheep. It is an abstract, I 3 disperse vith was a sheep, It is an abstract, I 3 don't like. I don't like the way that everything was the same. I think that was a lawed approach. Than rots atying he is incompetent; to you just don't corne or was a sheep model where the details from that like and the was a sling. I believe it was a sheep model. Don't you have to test models before you actually do them? 3 Lareally don't under	1	implantation test than just 14 days. I think	1	model. I don't know.
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57 (Pages 222 to 225)

	Page 226		Page 228
1	that area.	1	what I've found. I haven't well, I have
2	A Yes. So if you want to validate a functional	2	looked. That's what I know right now.
3	model, that's a different question. I think	3	Q So have we discussed ten?
4	what they did in this study is they just	4	A I don't have anything to add to ten.
5	implanted it adjacent to the tissue. I don't	5	Q And 11 is similar to number ten or how is
6	think it was intended to be a functional	6	that different from anything you talked about
7	sling model.	7	in Huskey?
8	They were just asking the question, well,	8	A Let me read it for a minute.
9	if I implant it here at the hernia abdominal	9	Q Sure.
10	wall versus here in the vaginal wall, do I	10	A I think the point in 11 is that when I say
11	see differences in cellular infiltration and	11	did not consider I think there is a lot of
12	contraction and those kinds it wasn't a	12	overlap with Huskey. They do not consider
13	this abdominal wall model has been around for	13	principles of biomaterial science by not
14	a while, right. So I think what they did	14	testing it in an oxidative environment using
15	that was different is they implanted it in	15	a known test that was known since the early
16	the vaginal wall as well.	16	90's. Even though they knew and from their
17	Q It wasn't validated, though, as between the	17	own studies, they saw evidence of oxidation
18	vaginal wall of the sheep and the abdominal	18	and degradation, they never tested it.
19	wall of the sheep?	19	So to me, biomaterial science, if I know
20	A I don't know what you mean by validated.	20	something is susceptible to oxidation, I need
21	When I think of validation, that's like a	21	to test that and assess it. And I guess what
22	functional model that you have to validate to	22	would be new here is that, you know, we have
23	make, so if you wanted to make a sheep sling	23	tested that. In one exemplar of TVT mesh, we
24	model, you would have to validate that. I	24	found that it can't oxidize. And that test
25	understand that, but I don't think that that	25	could have been done by Ethicon. That is
	Page 227		Page 229
1	is what they did.	1	what I'm saying in 11 that is new.
2	Q This wasn't a validated sheep model study?	2	Q You're saying that test could have been done
3	A I would say it wasn't a validated sling	3	by Ethicon?
4	model. They weren't modeling the sling in	4	A Yes.
5	the sheep and trying to draw some conclusion	5	Q But somebody at Ethicon would actually have
6	about how the sling would act in a human. I	6	to believe that this cobalt study that you
7	think they were just asking a question, how	7	referenced and the solutions are what
8	would this mesh infiltrate in these two	8	actually occurs from macrophages at an
9	different environments. That's what that	9	unknown concentration in the body, correct?
10	model was, which I think is a legitimate	10	MR. KUNTZ: Objection.
11	thing to do.	11	A Yes. And there is some well-trained
12	People have been implanting there is a	12	scientists at Ethicon. Those papers have
13	number of rat abdominal wall models in other	13	been cited dozens of times and are well
14	rodents and large animals. I don't think	14	established in the field. They are well
15	that is a I think that is a good approach.	15	known in the field. Those papers were
16	Q Have you ever seen it done before,	16	instrumental in discovering the problem of
17	implantation of mesh in a sheep or a large	17	the instability of polyether urethane
18	animal's vagina?	18	catheter leads, that these leads would
19	A That's the first I have seen it, but there	19	oxidize, degrade, and in some cases fail.
20	may be other studies.	20	Those products were withdrawn from the
21	Q Did you do any investigation to see whether	21	market.
22 23	the findings were consistent or inconsistent	22	So if I were at Ethicon, and I knew that
23	with other testing or whether anyone had tried to do that before?	23 24	story, I would be very worried about this, because it's the same type of problem, a
25	A I have looked for other studies and that's	25	chemical attack. It's just an environmental
∠ ⊃	A I have looked for other studies and that's	_ <u></u>	Chemical attack. It 8 just all chvilolillental

58 (Pages 226 to 229)

	Page 230		Page 232
1	stress cracking problem, where you have an	1	trial and tell the Perry jury that based on
2	oxidative environment and materials sensitive	2	the testing you did on that single TVT device
3	to oxidation and mechanical forces. All of	3	that there could be degradation in the human
4	those can lead to this environmental stress	4	body by a certain time point?
5	cracking in device failure.	5	MR. KUNTZ: Objection.
6	So if I were at Ethicon and I knew of	6	A I've not testified and I don't plan I've
7	those problems with those urethane catheter	7	been saying and I still say that it's
8	leads, one of the first things I would have	8	unpredictable. There is no certain time
9	done is tested these meshes in this oxidative	9	point. It's unpredictable.
10	environment so I would know.	10	BY MR. SNELL:
11	BY MR. SNELL:	11	Q Okay. I just want to make sure I understand
12	Q The urethane catheters, were those Ethicon	12	how far you were going to try to take this
13	products?	13	study.
14	A No. But a good biomaterials scientist	14	Just so we're crystal clear, you're not
15	recognizes that these are two polymers that	15	going to walk into that trial and say, at one
16	are sensitive to oxidation. And I would at	16	year, you can see degradation from the TVT
17	least want to know I would want to know,	17	mesh, and I know it because of the study I
18	does it degrade, does it oxidize, does it	18	did on the TVT device?
19	degrade. I think you have to ask that	19	A No, I'm not saying that.
20	question when you're designing a biomedical	20	Q Okay. Did you do power calculations on your
21	device, what's the material made of and is	21	TVT device study?
22	that a problem.	22	A It's an in vitro test. We typically do power
23	Q Well, there could be folks at Ethicon who	23	calculations on preclinical studies. But in
24	have relevant experience who look at the	24	the in vitro test, it's in vitro, where it's
25	paper by Anderson and this cobalt solution,	25	you know, it's
	Page 231		Page 233
1	and say that test doesn't actually look like	1	Q You need to do power calculations on the
2	it or is representative of the foreign body	2	front end of this test if you're going to try
3	reaction in the body. I mean, couldn't	3	to do statistical significant testing on the
4	scientists come to that conclusion?	4	back end, isn't that correct?
5	A They could. But, again, this is a	5	A My experience with power calculations, again,
6	well-accepted test that's been cited a lot	6	is typically in an in vivo study where we
7	and used a lot. I think it should at least	7	estimate it's so that we ensure that our
8	raise some questions, especially when you	8	study is power enough. If we estimate a
9	have your own studies showing evidence of	9	certain variance in a certain number is 10
10	oxidation. So it's not only the literature,	10	percent, we want to be able to power our
11	but it's also these own suture studies, the	11	study to make sure that we can see that
12	dog study, Guidon study, that showed evidence	12	10-percent effect.
13	of oxidation that should have sent off some	13	But this is an in vitro study, so, well,
14	red flags, hey, this material is sensitive to	14	we did the study, and either we will see a
15	oxidation, why don't we test it. That is	15	significant difference or we won't. That's
16	what I am saying.	16	what it is. If we don't see a significant
17	MR. SNELL: Let's take a break	17	difference, then maybe the study wasn't
18	here. We've been going for a while.	18	underpowered, but we report that it is if
19	(A brief recess is taken from	19	it's not significant. But it's either
20	4:30 to 4:40 p.m.)	20	significant or it's not.
21 22	BY MR. SNELL:	21	I mean, the reason you do a power study
177	Q Doctor, I want to circle back around to your	22	in a preclinical study is to make sure you
	test the testing that you were inlined in	1 7 7	horro got anough animals to dotd !
23	test, the testing that you were involved in.	23	have got enough animals to do your study. In
	test, the testing that you were involved in. I just want to make sure that based on that test, you're not going to come into	23 24 25	have got enough animals to do your study. In an in vitro study, well, if we don't see significant differences in the in vitro

59 (Pages 230 to 233)

	Page 234		Page 236		
1	study, then our conclusion would be that it's	1	can't see differences, you don't know it's		
2	just not a significant difference.	2	part of justifying the numbers of animals		
3	Q Isn't it true, Doctor, that if you do not do	that you're going to use in your test. But			
4	power calculations on the front end of a	4	if you have two sets of data, you can compare		
5	study, you can't say that there are	5	whether they are statistically different or		
6	statistically significant findings on the	6	not. This is what people do. It's an in		
7	back end, because you haven't even assessed	7	vitro test. I just don't know where you are		
8	whether you have an adequately powered study?	8	coming from.		
9	MR. KUNTZ: Objection.	9	Q When you do studies, you want to have		
10	A I don't think that's true in in vitro	10	adequate sample sizes so that you can tell if		
11	studies. I don't see people doing this. I	11	the results are meaningful. That's a fair		
12	don't see papers where people power their in	12	statement, right?		
13	vitro studies. We typically do enough	13	A Yes, but you can tell if the results are		
14	replicates that we can calculate a standard	14	significantly different if you see a		
15	deviation and run an ANOVA or a t-test or	15	significant difference. You can calculate a		
16	something, but we don't in a clinical	16	P value. You can do a t-test. You can do an		
17	trial and in an animal study, we do power	17	ANOVA on that date. If you don't see a		
18	analysis all the time, but I just I	18	significant difference, then one reason could		
19	don't	19	be you didn't have enough replicates. But if		
20	BY MR. SNELL:	20	you see a significant difference, I don't		
21	Q Did you estimate the potential rate of error	21	understand how it's not significant. If you		
22	in your study before it was done?	22	see a significant difference between two		
23	A Potential rate of error in	23	groups, they're different. That means the		
24	Q In finding discrepant findings?	24	differences are I don't understand. I		
25	A I just don't know where you are going with	25 mean, this is like statistics that you learn			
	Page 235		Page 237		
1	this.	1	in school. I mean, comparing two		
2	Q Did you do it or didn't you do it? Did you	2	populations.		
3	do a calculation to assess the potential rate	3	Q Yeah, but here the two populations was a TVT		
4	of error before you started that study on the	4	device and a polypropylene pellet. It wasn't		
5	TVT device?	5	100 TVT devices and 100 pellets, was it?		
6	A We didn't do that calculation.	6	A You are so confused on statistics. I made		
7	Q Did you estimate the variance as you noted	7	this clear. We tested one exemplar, but we		
8	earlier?	8	cut multiple pieces from each exemplar. So		
9	A But this isn't the way statistics works. I	9	we have replicates. So we can say,		
10	mean, if we have two populations, we can	10	statistically, in that mesh that we tested is		
11	compare by a t-test. We can compare those	11	there more oxidation from the FTIR spectra at		
12	populations and draw within we assess P to	12	week five compared to week four compared to		
13	be .05, and so with this value of P, we can	13	these other weeks.		
14 15	say it's significant or not significant.	14 15	We can do that test through even just		
16	That's typically what people do in in vitro studies. We say P is .05, and then we do	16	we could do a two-way ANOVA to compare changes in time and changes in the mesh or		
17	this we can calculate a P value. You can	17	between groups and as a function of time. We		
18	do it either way.	18	can do that analysis and that can be		
19	But if you have two populations, you can	19	that's what people do all the time.		
20	compare those populations using statistical	20	Q You can't do that analysis as between the		
21	analyses. My experience with these power	21	control, though, because you didn't run all		
22	analyses is a lot of it comes down to an	22	of the same tests at the same time, correct?		
23	ethics concern. It's not ethical to do an	23	A I don't remember the details of that. We ran		
24	animal study that is insufficiently powered.	24	the control went out to four weeks. We ran		
25	Because if you do the study, and you	25	the TVT out to five, and I think we might		

60 (Pages 234 to 237)

	Page 238		Page 240
1	have had one that went to six weeks, but we	1	piece of mesh in Mrs. Perry's body became
2	just didn't have enough sample to go out that	2	unstable from a polymer standpoint?
3	far.	3	A No, I'm not.
4	But we can do all of these statistical	4	Q Are you aware of any evidence that the piece
5	analysis, and I will bring it to trial, and	5	of mesh in Mrs. Perry became brittle?
6	you can come at me with whatever you want	6	A No, I'm not aware of that.
7	about statistics, but I just don't see where	7	Q Are you aware of any evidence that the piece
8	you are coming from with this. I mean, we	8	of mesh in Mrs. Perry degraded?
9	can do a statistical test to see whether	9	A No.
10	there is differences at least in the function	10	Q I didn't ask you at the beginning. Have you
11	of time. That's how we are going to assess	11	given testimony at all since the Huskey trial
12	whether it is induced is the amount of	12	as an expert
13	oxidation at week five significantly greater	13	A I provided this listing.
14	than what we see at weeks, four, three, two,	14	Q against anybody? I think you're right.
15	one or zero.	15	MR. KUNTZ: He gave you an
16	Q That hasn't been done, though, to this point?	16	updated copy since the Huskey trial. I think
17	Or you didn't bring that with you today,	17	you have it.
18	right?	18	A I gave testimony in Boston Scientific since
19	A It hasn't been done. We're working on it.	19	the Huskey trial.
20	Q The tensile string, is that anything that you	20	MR. SNELL: I have it right
21	tested in this test of the TVT versus the	21	here. I'm going to mark it.
22	control?	22	(Deposition Exhibit No. 5 was
23	MR. KUNTZ: Objection.	23	marked for identification.)
24	A We didn't measure tinsel strength. This	24	BY MR. SNELL:
25	takes a lot of material. And, again, it	25	Q Doctor, I'm handing you Exhibit 5. Tell me
	Page 239		Page 241
1		1	
1 2	doesn't answer the question of whether it can	1 2	what that is, please.
			what that is, please. A This is a listing of cases in which I
2	doesn't answer the question of whether it can be oxidized. Tensile strength is a bulk	2	what that is, please.
2 3	doesn't answer the question of whether it can be oxidized. Tensile strength is a bulk test. So because it is a bulk test, it's	2 3	what that is, please. A This is a listing of cases in which I provided testimony in the last four years.
2 3 4	doesn't answer the question of whether it can be oxidized. Tensile strength is a bulk test. So because it is a bulk test, it's testing the whole material. You may or may	2 3 4	what that is, please. A This is a listing of cases in which I provided testimony in the last four years. And there are five cases listed here in 2013
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2 3 4 5 6	doesn't answer the question of whether it can be oxidized. Tensile strength is a bulk test. So because it is a bulk test, it's testing the whole material. You may or may not see the problem with doing a tensile strength test is	2 3 4 5 6	what that is, please. A This is a listing of cases in which I provided testimony in the last four years. And there are five cases listed here in 2013 and 2014. MR. SNELL: I'd like to mark
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61 (Pages 238 to 241)

	Page 242		Page 244			
1	Q What are the other methods?	1	A We can buy those from companies. There is an			
2	A The microscopy methods with Dr. Iakovlev.	2	immortalized cell line that you can buy.			
3	Q Are you aware of any evidence that the piece	3	Q So my question to you, then, is, do you know			
4	of mesh in Mrs. Perry has or had	4	whether there are available for purchase or			
5	environmental stress cracking?	5	use quiescent macrophage cells?			
6	A I'm not aware of any evidence.	6	1 0			
7	Q Earlier we talked about the concept of	7	that doesn't mean that they happen in the			
8	macrophages in foreign giant body cells being	8	human body. Again, without seeing a			
9	quiescent?	9				
10	A Yes.	10	Q How would one definitively prove that			
11	Q You are aware that those cells can be	11	macrophages in giant cells become quiescent			
12	quiescent, correct?	12	in the body?			
13	A I'm aware that this is an active area of	13	A Well, I would challenge it with a foreign			
14	investigation. I'm aware that there is a lot	14	body, and different time points, harvest the			
15	of research activity trying to make these	15	cells, and stain for myeloperoxidase. But			
16	cells quiescent or inactivate them. I'm not	16	it's to assess that they are actually			
17	aware of any reports that have definitely	17	quiescent I mean, you have to count the			
18	proven they're quiescent or what makes them	18	number of cells, and then look at the amount			
19	quiescent. I would be happy to look at it.	19	of myeloperoxidase, look for degradation. It			
20	I'm familiar with this idea, but I'm not	20	would be difficult to show that they are			
21	familiar with any studies that have proven	21	completely quiescent.			
22	that or shown under what conditions that can	22	Q So what would you have to do to prove that			
23	occur.	23	those cells are activated every day of the			
24	Q You are aware actually that scientists are	24	year for ten years? You would have to do the			
25	able to now incubate and generate quiescent	25	same test, wouldn't you?			
	Page 243		Page 245			
1	tissue macrophages for use in studies? Don't	1	A We talked about this earlier. What I know is			
2	you know that?	2	Dr. Iakovlev, whenever we stain for			
3	A Well, I would like to see the document you're	3	myeloperoxidase, we see it. So does that			
4	referring to. I just said I haven't seen	4	conclusively prove that every cell is always			
5	that. I am aware of this idea, but I haven't	5	Dr. Anderson's 2008 review says that these			
6	seen that study. I would be happy to look at	6	cells are activated and adherent, and this			
7	it, but I	7	reaction doesn't stop. That's what he says.			
8	Q My question is not pertaining to a specific	8	Q How is that proof? What test has been done			
9	study. It's do you know whether scientists	9	under the proper methodology that shows that			
10	have generated incubated quiescent tissue	10	those cells are always activated every day			
11	macrophages for use in studies?	11	for a long period of time? Has anybody done			
12	A I'm not sure what you're referring to. I	12	such a test?			
13	mean, I would have to see a study to I'm	13	A Not that I know of. But why would they stop?			
14	aware of this area of research, but I can't	14	Why would they			
15 16	comment on it without talking about a	15 16	Q Well, I understand that Dr. Anderson may			
17	specific study at least. What am I going to	17	believe that or he wrote something to that			
18	say? I don't know where	18	effect. But has that methodology been tested to show that they are always in an activated			
19	Q Let me ask you this. You know that scientists manufacture different cell lines	19	state day after day after day?			
20	for use in studies, correct?	20	A All I can say is that in my experience with			
21	A There are different permanent cell lines that	21	this is that they are activated. When I			
22	are used in cell culture. I use them in my	22	talked to Dr. Iakovlev, did you stain for			
1 4 4	own lab.	23	myeloperoxidase, his response was, why would			
2.3						
23 24						
23 24 25	Q So somebody, scientists or companies make those, correct?	24 25	I stain for myeloperoxidase, it has to be there.			

62 (Pages 242 to 245)

	Page 246		Page 248
1	Q Dr. Iakovlev assumes it's there. But he has	1	A You already asked this. I said I don't know
2	not tested for myeloperoxidase on a	2	of a study that showed that. I'm just going
3	continuous basis, daily or weekly basis in	3	from my own experience.
4	samples?	4	Q Do you know if Dr. Iakovlev has done any type
5	A I tell you what, I think most people will be	5	of longitudinal study of myeloperoxidase and
6	convinced by it.	6	what it should show when properly applied to
7	Q Can you answer that question, please? That	7	samples from the same source over time?
8	is what Dr. Iakovlev believes, right?	8	A I mean, he's a pathologist. He looks at
9	A Yeah.	9	patient explants. You can't do a study like
10	Q But has he tested for myeloperoxidase in the	10	that in patients, so I don't believe that he
11	same samples longitudinally week after week	11	has done that study.
12	after week after week to see that those are	12	Q Did you bring anything else that we haven't
13	activated?	13	marked?
14	A Not to my knowledge.	14	A I think that's it.
15	Q All right. And you haven't done that type of	15	Q When you do statistical significance testing,
16	testing, correct?	16	do you try to generate confident symbols as
17	A No. But in my experience, when I see	17	well?
18	macrophages and stain for myeloperoxidase,	18	A Sometimes. It depends on what we're trying
19	I've not seen this type of stain. I need to	19	to do. Sometimes when we establish P at .05,
20	qualify my comment. When I see this adherent	20	sometimes we can calculate a P value. We've
21	macrophages in the foreign giant body cells	21	done several different things.
22	in my work, they appear to be activated.	22	Q Have you actually personally ever calculated
23	Q All right. You can see macrophages and	23	a Bonferroni correction for multiple
24	they're not activated. That is well known,	24	comparison?
25	correct?	25	A When I was in graduate school. My students
	Page 247		Page 249
1	A I don't know that I would say that that is	_	
2		1	do those calculations now, and I review them.
1 4	well-known. I don't know under what	1 2	do those calculations now, and I review them. There are software programs that you can use
3			There are software programs that you can use
	well-known. I don't know under what	2	There are software programs that you can use to do this. It's pretty routine, I think.
3	well-known. I don't know under what conditions I mean, I would have to see a study.	2 3	There are software programs that you can use
3 4	well-known. I don't know under what conditions I mean, I would have to see a	2 3 4	There are software programs that you can use to do this. It's pretty routine, I think. Q The software plugs in the number of tests and
3 4 5	well-known. I don't know under what conditions I mean, I would have to see a study. Q Well, let me make it simple. Can macrophages	2 3 4 5	There are software programs that you can use to do this. It's pretty routine, I think. Q The software plugs in the number of tests and the time points and it generates
3 4 5 6	well-known. I don't know under what conditions I mean, I would have to see a study. Q Well, let me make it simple. Can macrophages be present and they're not activated?	2 3 4 5 6	There are software programs that you can use to do this. It's pretty routine, I think. Q The software plugs in the number of tests and the time points and it generates A We can do this with software, yeah.
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63 (Pages 246 to 249)

	Page 250		Page 252
1	Q Where was this at?	1	to problems such as pain, erosion. The basis
2	A The AICHE, it's the American Institute of	2	for this opinion is the Clave, Costello, Wood
3	Chemical Engineers. If you would like, I can	3	papers where they show changes in the mesh,
4	circle it on my CV. Would that help you?	4	and then how that resulted in degradation.
5	Q Sure. That's fine. Or if you just want to	5	And these are all complications, so these are
6	look at your CV and tell me what page or	6	meshes that failed.
7	number.	7	And my opinion is that these changes in
8	A That's fine too. On the CV, it's	8	the mesh contributed to those complications
9	presentation number 154.	9	like pain and erosion. Brittle plastic can
10	Q Was that a presentation that you actually	10	cause pain. Embrittlement can cause stress
11	gave and presented or did someone else do it?	11	shielding between the host tissue and the
12	A Dr. Dunn and I both gave the presentation.	12	implant, which can lead to poor integration,
13	Q Was it presented orally?	13	erosions, and things like that. These are
14	A It was.	14	all points that I made previously in Huskey.
15	Q Okay. So I would like to request a copy of	15	Q In Huskey, though, you didn't testify about
16	that.	16	that at trial as I recall it because you're
17	Did you have to prepare a manuscript in	17	not a medical doctor. Is that consistent
18	connection with that?	18	with your recollection?
19	A No. We submitted a short abstract, which is	19	MR. KUNTZ: Objection. Go
20	available online. We elected not to submit	20	ahead.
21	an extended abstract.	21	A I think the Judge may have limited what I
22	Q What was the reason why you didn't submit an	22	would have liked to have said, but I believe
23	extended abstract?	23	it's in the deposition. I don't think
24	A We typically don't do that for that meeting.	24	there is any change in what I'm saying, in
25	Q Is that the only presentation you have made	25	what I've been saying in these depositions.
	Daga 251		
	Page 251		Page 253
1	concerning the TVT mesh?	1	Q And just so I'm clear, you didn't conduct any
2	concerning the TVT mesh? A Yes.	2	Q And just so I'm clear, you didn't conduct any type of differential diagnosis to assess the
2 3	concerning the TVT mesh? A Yes. Q Have you made any other presentations that	2	Q And just so I'm clear, you didn't conduct any type of differential diagnosis to assess the cause of dyspareunia or pain or the potential
2 3 4	concerning the TVT mesh? A Yes. Q Have you made any other presentations that concern transvaginal mesh?	2 3 4	Q And just so I'm clear, you didn't conduct any type of differential diagnosis to assess the cause of dyspareunia or pain or the potential causes, correct?
2 3 4 5	concerning the TVT mesh? A Yes. Q Have you made any other presentations that concern transvaginal mesh? A That's the only one.	2 3 4 5	Q And just so I'm clear, you didn't conduct any type of differential diagnosis to assess the cause of dyspareunia or pain or the potential causes, correct? A No.
2 3 4 5 6	concerning the TVT mesh? A Yes. Q Have you made any other presentations that concern transvaginal mesh? A That's the only one. Q On opinion number one, you say chemical	2 3 4 5 6	 Q And just so I'm clear, you didn't conduct any type of differential diagnosis to assess the cause of dyspareunia or pain or the potential causes, correct? A No. Q You didn't rule out any other cause or
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64 (Pages 250 to 253)

on those, correct? A No. Q You didn't assess causation by ruling in or ruling out different causes, correct? A No. I didn't do that. A Do, I didn't do that. G Q In the testing that Dr. Kammerer did we taked about earlier, where in the first to present a deal to the control of the mesh, the mesh causes and the laser-cut were similar, do you dispute that finding? A I don't dispute the finding that of the very low elongation. They are similar but— Q O Jod you look at the clinical expert report that was done by two medical doctors at Ethicon with regard to the laser-cut mesh and elongation? A I think I reviewed that document, but I can't remember what it said right now. A I think I reviewed that document, but I can't remember what it said right now. A I think I reviewed that document, but I can't remember what it said right now. A I think I reviewed that document, but I can't remember what it said right now. Page 255 A No. I have not done that. I relied on the Ethicon documents. A I would have to look at it. A Yeach or was a way the more and the might have been a defense withink in word then, but I bank it move the forward. A Page 1 A D I don't know from, but I found it when the last finding? A I would have to look at it. A J would have to look at it again to see what it say any the way it is a word of the west it. A I would have to look at it again to see what are in play during implantation? A I would have to look at it. A Page 2 ST A No. I have not done that. I relied on the Ethicon documents. Ethicon documents. A Page 2 ST A No. I have not done that. I relied on the Ethicon documents. A Page 2 ST A No. I have not done that. I relied on the Ethicon documents. A Page 2 ST A No. I have not done that. I relied on the Ethicon documents. A Page 2 ST A Page 2 ST A Page 2 ST A Page 2 ST A No. I have not done that. I relied on the Ethicon documents. BY MR. SNELL: A Page 2 ST A Page 2 ST A No. I have not done that. I relied on the Ethicon documents. BY MR. SNELL: A Page 2 ST A Pag		Page 254		Page 256		
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65 (Pages 254 to 257)

	Page 258		Page 260
1	Q They really are, sir.	1	stopped because it's not proper for me to
2	MR. KUNTZ: Hold on. I'm going	2	I don't know whether he is a defense witness
3	to object. You are showing him one document,	3	or not, so I would have to resolve this
4	and I just made my objection. It is not a	4	before I would really do anything.
5	straight forward question when you're not	5	Q You did speak to a female urogynecologist?
6	showing him the whole website. And he just	6	A Yes. I can't remember her name.
7	said where is the website that shows all of	7	Q Or do you know if she was a urologist?
8	the complications they're treating for mesh.	8	A I can't remember. She was in this group.
9	So that is not a straight forward question.	9	She has experience with mesh revisions. And
10	MR. SNELL: That's not even a	10	one of my students, one of my medical
11	proper objection. That's not a proper	11	students, did a rotation with her, and I
12	objection in California. That's beyond a	12	contacted her, I think, in September, but I
13	speaking objection.	13	dropped it because of this concern about
14	MR. KUNTZ: You just said all of	14	litigation.
15	my questions are straight forward. And this	15	Q Okay. Do you have any understanding of the
16	is very much a trick question and not a	16	antioxidants that are in the mesh for the TVT
17	straight forward question. So don't make	17	Abbrevo?
18	your comments unless you	18	A To my knowledge, they are the same as they
19	MR. SNELL: Let's try it again	19	are in proline resin that I talked about at
20	and knock off the ridiculous speaking	20	trial.
21	objections.	21	Q Okay. One of the opinions you gave in Huskey
22	MR. KUNTZ: Show him the whole	22	was less mesh is better; is that correct?
23	website.	23	A That's correct.
24	MR. SNELL: Give the man a	24	Q Why don't you give that opinion here?
25	computer. You can have him look at anything.	25	A Why don't I give that opinion?
	Page 259		Page 261
1	MR. KUNTZ: You bring documents	1	Q Why aren't you giving that opinion here?
2	and ask him questions. My job is to show up	2	A I don't think that was specified as an
3	with	3	opinion. I don't recall that. I thought it
4	MR. SNELL: You are wasting my	4	was in the body of the report. I don't
5	time. You're giving speaking objections that	5	
6)	remember that being spelled out as a specific
	are absolutely improper in California.	6	remember that being spelled out as a specific opinion.
7	are absolutely improper in California. MR. KUNTZ: You are asking trick	1	opinion.
7 8	are absolutely improper in California. MR. KUNTZ: You are asking trick questions, and that's what he told you.	6	
8	MR. KUNTZ: You are asking trick	6 7	opinion. Q Do you know Abbrevo uses less mesh that
	MR. KUNTZ: You are asking trick questions, and that's what he told you.	6 7 8	opinion. Q Do you know Abbrevo uses less mesh that TVT-O, don't you?
8 9	MR. KUNTZ: You are asking trick questions, and that's what he told you. MR. SNELL: It's not a trick	6 7 8 9	opinion. Q Do you know Abbrevo uses less mesh that TVT-O, don't you? A What do you mean by uses less mesh? The area
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66 (Pages 258 to 261)

	Page 262		Page 264
1	A To my knowledge, and I believe the density is	1	what we have, and preparing for trial, those
2	the same as well.	2	types of activities.
3	Q When you say density, what do you mean by	3	Q All right. Is there a list of analyses that
4	that?	4	you can tell me or tell the court reporter
5	A Grams per square meter.	5	that you plan to do?
6	Q Okay. But we can agree there is less mesh	6	A Plan to do testing.
7	with TVT Abbrevo than TVT-O?	7	Q With the testing or pertaining to this case?
8	A There is less mesh the way you say it, I	8	A It's the statistical analysis and writing the
9	guess it's true.	9	paper. That's it.
10	Q Now, do you have an opinion as to whether TVT	10	Q What will you do if you do the statistical
11	Abbrevo is the better or a safer device than	11	calculations and they turn out to not be
12	the TVT-O?	12	statistically significant?
13	MR. KUNTZ: Objection.	13	A Report it as not significant, like we always
14	A No. I'm not comparing it to TVT-O.	14	do.
15	MR. SNELL: I think I'm about	15	Q What else?
16	done. Let me look back through and see if	16	A What do you mean what else?
17	there is anything else.	17	Q What will you do to try to understand why
18	(A brief recess is taken from	18	they were not statistically significant?
19	5:30 to 5:40 p.m.)	19	A I don't know. I would have to think about
20	BY MR. SNELL:	20	that at the time it I don't think that
21	Q Just a few more questions, Doctor. So I'm	21	that is what is going to happen. The peak is
22	going to request that whatever the materials	22	ten times bigger, and the aragores (phonetic)
23	that weren't provided on the testing that was	23	aren't that I believe it's going to be
24	done be provided. I'm going to leave the	24	significant, and if it's not, then I will
25	deposition open.	25	figure out what to do when that happens. I'm
	Page 263		Page 265
1	Is there anything you believe is	1	not going to misrepresent data.
2	important to your analysis	2	MR. SNELL: That's fine. I'm
3	MR. KUNTZ: Hold on. We're not	3	going to leave the door open. I know counsel
4	leaving the deposition open.	4	has a question or two.
5	MR. SNELL: You can say what you	5	MR. ROSEN: I've got one
6	want to say. I'm leaving it open. I don't	6	question.
7	have all of the documents.	7	CROSS-EXAMINATION
8	MR. KUNTZ: California law is	8	BY MR. ROSEN:
9	you can argue	9	Q Good evening, Mr. Guelcher. My name is
10	MR. SNELL: I'm not going to	10	Dr. Rosen. I'm with Boyce Schaeffer
11	argue with you. I'm either right or wrong.	11	Mainieri. We represent Dr. Luu. I just have
12	MR. KUNTZ: Okay.	12	one question.
13	MR. SNELL: I'm either right or	13	Do you intend to offer any opinions
14	wrong.	14	regarding Dr. Luu at trial in this matter?
15	BY MR. SNELL:	15	A I do not. My testimony is about the mesh and
16		16	how it changes after implantation.
	Q Is there anything you believe is important in	1 - 0	
17	your opinions and analyses that we have not	17	MR. ROSEN: That's all. Thank
18	your opinions and analyses that we have not discussed today?	17 18	MR. ROSEN: That's all. Thank you.
18 19	your opinions and analyses that we have not discussed today? A I believe we have discussed everything that	17 18 19	MR. ROSEN: That's all. Thank you. MR. KUNTZ: Dr. Guelcher, I have
18 19 20	your opinions and analyses that we have not discussed today? A I believe we have discussed everything that is important.	17 18 19 20	MR. ROSEN: That's all. Thank you. MR. KUNTZ: Dr. Guelcher, I have a few questions for you.
18 19 20 21	your opinions and analyses that we have not discussed today? A I believe we have discussed everything that is important. Q Now, is there any work that you are planning	17 18 19 20 21	MR. ROSEN: That's all. Thank you. MR. KUNTZ: Dr. Guelcher, I have a few questions for you. CROSS-EXAMINATION
18 19 20 21 22	your opinions and analyses that we have not discussed today? A I believe we have discussed everything that is important. Q Now, is there any work that you are planning on doing with this case after today?	17 18 19 20 21 22	MR. ROSEN: That's all. Thank you. MR. KUNTZ: Dr. Guelcher, I have a few questions for you. CROSS-EXAMINATION BY MR. KUNTZ:
18 19 20 21 22 23	your opinions and analyses that we have not discussed today? A I believe we have discussed everything that is important. Q Now, is there any work that you are planning on doing with this case after today? A No.	17 18 19 20 21 22 23	MR. ROSEN: That's all. Thank you. MR. KUNTZ: Dr. Guelcher, I have a few questions for you. CROSS-EXAMINATION BY MR. KUNTZ: Q With respect to the studies you've talked
18 19 20 21 22	your opinions and analyses that we have not discussed today? A I believe we have discussed everything that is important. Q Now, is there any work that you are planning on doing with this case after today?	17 18 19 20 21 22	MR. ROSEN: That's all. Thank you. MR. KUNTZ: Dr. Guelcher, I have a few questions for you. CROSS-EXAMINATION BY MR. KUNTZ:

67 (Pages 262 to 265)

	Page 266	Page 268
1	studies or documents or data that you can	of the response, part of the answer.
2	review independently of Dr. Dunn, correct?	2 I'm done. Thank you.
3	A Yes, that's correct.	3 (Deposition was adjourned at 5:50
4 5	MR. SNELL: Objection. You've	4 p.m.)
6	got to give me a chance to object. Leading,	5 * * * 6
7	compound. Go ahead. BY MR. KUNTZ:	7
8		8
9	Q You repeatedly in your practice are going to have expertise reviewing those types of	9
10	studies, SEM, FTIR, and XPS?	10
11	MR. SNELL: Objection. Leading	11
12	compound. Go ahead.	12
13	A Yes, I do.	13
14	Q And if Ethicon did those studies or had those	14
15	types of documents, you could review those	15
16	independently, correct?	16
17	MR. SNELL: Same objections.	17
18	A Yes, I could.	18
19	Q The last question I have. Is there any	19
20	peer-reviewed article that you're aware of	20
21	that shows or supports the notion that	21
22	macrophages in foreign body giant cells can	22
23	be deactivated?	23
24	A I'm not aware of such an article.	24
25	MR. KUNTZ: Okay. No more	25
	Page 267	Page 269
1	questions.	1 STATE OF KENTUCKY)
2	REDIRECT EXAMINATION	2)
3	BY MR. SNELL:	3 COUNTY OF DAVIESS)
4	Q Are you aware of any book chapters, any	4 5 I, MICHELLE E. KERR, A NOTARY PUBLIC AT LARGE IN
5	articles in the peer-reviewed literature that	5 I, MICHELLE E. KERR, A NOTARY PUBLIC AT LARGE IN 6 AND FOR THE COMMONWEALTH OF KENTUCKY, DO HEREBY
6	says that macrophages can indeed be	7 CERTIFY:
7	deactivated?	8 THAT SAID DEPOSITION WAS TAKEN STENOGRAPHICALLY
8	A I'm not aware of those articles. That's what	9 AND ELECTRONICALLY BY ME AND THAT THE TYPEWRITTEN
9	I said earlier.	10 TRANSCRIPT ABOVE IS A TRUE RECORD OF THE
10	Q But you have seen it in the literature or in	11 TESTIMONY GIVEN; THAT I ALSO RECORDED AND
11	books that macrophages can be quiescent?	12 TRANSCRIBED ANY AND ALL OBJECTIONS MADE BY COUNSEL 13 AND THE REASONS THEREFORE; AND THAT I AM NOT A
12	A That's not what I said. I'm familiar with	14 RELATIVE OR EMPLOYEE OR ATTORNEY OR COUNSEL OF ANY
13	this idea of reprogramming macrophages, but I	15 OF THE PARTIES, NOR A RELATIVE OR EMPLOYEE OF SUCH
14	am not familiar with any studies that have	16 ATTORNEY OR COUNSEL, NOR AM I FINANCIALLY INTERESTED
15	shown that this has been done or under what	17 IN THIS ACTION.
16	conditions it happens. I mean, I'm familiar	18
17	with the idea. I'm just not familiar with	19 20 IN WITNESS WHEREOF, I HAVE HEREUNTO SET MY HAND
18	such a study is what I'm saying.	21 AND AFFIXED MY NOTARIAL SEAL ON THIS DAY OF
19	Q You're not familiar with such a study that	22 DECEMBER, 2014.
20	shows that macrophages are activated	
21	longitudinally every day for years and years?	MICHELLE E. KERR, NOTARY PUBLIC
22 23	A No one has proven that, but Anderson teaches	24 25 M.C
24	they're activated when they adhere. That's what it says.	25 My Commission Expires: March 21, 2017
25	MR. SNELL: Move to strike part	March 21, 2017 March 21, 2017
- 4 -	wite brille. Wove to surke part	,,

68 (Pages 266 to 269)

	Page 2	270			Page 272
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 7 18 19 20 21 22 23 24 25 26 27 26 27 27 27 27 27 27 27 27 27 27 27 27 27	Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the errata sheet and date it. It will be attached to your deposition. It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.		1 2 3 4 5 6 7 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	ACKNOWLEDGMENT OF DEPONENT I,	
25	Page 2	271	25		Page 273
1 2345678910112 1314151617 189201223 2425	ERRATA PAGE LINE CHANGE REASON:		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	LAWYER'S NOTES PAGE LINE	

69 (Pages 270 to 273)

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